DOCKET

SUPREME COURT

OF THE UNITED STATES

No. 09-475
Title: Monsanto Company, et al., Petitioners
v.
Geertson Seed Farms, et al.
Docketed: October 23, 2009
Lower Ct: United States Court of Appeals for the Ninth Circuit
Case Nos.: (07-16458, 07-16492, 07-16725)
Decision Date: June 24, 2009
Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Sep 11 2009	Application (09A254) to extend the time to file a petition for a writ of certiorari from September 22, 2009 to October 22, 2009, submitted to Justice Kennedy.
Sep 17 2009	Application (09A254) granted by Justice Kennedy extending the time to file until October 22, 2009.
Oct 22 2009	Petition for a writ of certiorari filed. (Response due November 23, 2009)
Nov 3 2009	Order extending time to file response to petition to and including December 23, 2009, for all respondents.
Nov 23 2009	Brief amici curiae of American Farm Bureau Federation, et al. filed.
Nov 23 2009	Brief amicus curiae of PhytaGro, LLC filed.
Nov 23 2009	Brief amicus curiae of Washington Legal Foundation filed.
Dec 23 2009	Brief of respondent Federal Respondents in opposition filed.
Dec 23 2009	Brief of respondents Geertson Seed Farms, et al. in opposition filed.
Dec 30 2009	DISTRIBUTED for Conference of January 15, 2010.
Dec 30 2009	Reply of petitioners Monsanto Company, et al. filed. (Distributed)
Jan 15 2010	Petition GRANTED. The brief of petitioners is to be filed on or before Thursday, February 25, 2010. The brief of respondents is to be filed on or before Thursday, March 25, 2010. A reply brief, if any, is to be filed in accordance with Rule 25.3 of the Rules of this Court. Justice Breyer took no part in the consideration or decision of this petition.
Feb 2 2010	Consent of petitioners to the filing of amicus curiae briefs in support of either party or neither party filed.
Feb 16 2010	SET FOR ARGUMENT ON Tuesday, April 27, 2010.
Feb 25 2010	The time within which to file the joint appendix and petitioners' briefs on the merits is extended to and including March 2, 2010.
Feb 25 2010	The time within which to file respondents' brief on the merits is extended to and including March 29, 2010.

Mar 1 2010	Brief of petitioners Monsanto Company, et al. filed.
Mar 1 2010	Joint appendix filed (2 volumes). (Statement of costs received.)
Mar 2 2010	Brief of respondent Federal Respondents in support of petitioners filed.
Mar 5 2010	CIRCULATED.
Mar 5 2010	Brief amicus curiae of Pacific Legal Foundation filed. (Distributed)
Mar 8 2010	Brief amici curiae of American Sugarbeet Growers Association, et al. filed. (Distributed).
Mar 8 2010	Brief amici curiae of American Farm Bureau Federation, et al. filed. (Distributed)
Mar 8 2010	Record received from U.S.C.A. for 9th Circuit. (1 envelope)
Mar 8 2010	Brief amici curiae of Washington Legal Foundation, et al. filed. (Distributed)
Mar 8 2010	Brief amici curiae of Chamber of Commerce of the United States of America, et al. filed. (Distributed)
Mar 12 2010	Record received from U.S.D.C. for Northern District of California
Mar 25 2010	Consent to the filing of amicus briefs, in support of either party or of neither party, received from the Solicitor General.
Mar 26 2010	Consent to the filing of amicus curiae briefs in support of either party or neither party received from counsel for the respondents.
Mar 29 2010	Brief of respondents Geertson Seed Farms, et al. filed. (Distributed)
Apr 1 2010	Motion for divided argument filed by Federal Respondents in support of petitioners.
Apr 5 2010	Brief amici curiae of Natural Resources Defense Council, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of Dinah Bear, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of People of the State of California, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of Arkansas Rice Growers Association, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of Cropp Cooperative, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of Defenders of Wildlife, et al. filed. (Distributed)
Apr 5 2010	Brief amici curiae of Union of Concerned Scientists, et al. filed. (Distributed)
Apr 16 2010	Motion for divided argument filed by the Solicitor General GRANTED. Justice Breyer took no part in the consideration or decision of this motion.
Apr 20 2010	Reply of petitioners Monsanto Company, et al. filed. (Distributed)
Apr 20 2010	Reply of respondent Federal Respondents in support of petitioners filed. (Distributed)
Apr 27 2010	Argued. For petitioners: Gregory G. Garre, Washington, D. C. For federal respondents supporting petitioners: Malcolm L. Stewart, Deputy Solicitor General, Department of Justice, Washington, D. C. For respondent Geertson Seed Farms, et al.: Lawrence S. Robbins, Washington, D. C.

PETITION FOR WRIT OF CERTIORARI

Supreme Court, U.S.
FILED

09-475 OCT 22 2009

No. OFFICE OF THE CLERK

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
PETITIONERS,

v.

GEERTSON SEED FARMS, ET AL.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In this case, after finding a violation of the National Environmental Policy Act ("NEPA"), the district court imposed, and the Ninth Circuit affirmed, a permanent nationwide injunction against any further planting of a valuable genetically-engineered crop, despite overwhelming evidence that less restrictive measures proposed by an expert federal agency would eliminate any non-trivial risk of harm. The questions presented are:

1. Whether the Ninth Circuit erred in holding that NEPA plaintiffs are specially exempt from the requirement of showing a likelihood of irreparable harm to obtain an injunction.

2. Whether the Ninth Circuit erred in holding that a district court may enter an injunction sought to remedy a NEPA violation without conducting an evidentiary hearing sought by a party to resolve genuinely disputed facts directly relevant to the appropriate scope of the requested injunction.

3. Whether the Ninth Circuit erred when it affirmed a nationwide injunction entered prior to this Court's decision in *Winter v. NRDC*, 129 S. Ct. 365 (2008), which sought to remedy a NEPA violation based on only a remote possibility of reparable harm.

LIST OF PARTIES AND RULE 29.6 STATEMENT

The petitioners are Monsanto Company ("Monsanto"), Forage Genetics International, LLC ("FGI"), Daniel Mederos, and Mark Watte.

Monsanto Company is a publicly traded company and has no parent corporations. Only one owner holds more than a 10% stake in Monsanto: FMR Corporation. FMR Corporation is not a publicly traded company.

On December 18, 2007, then intervenor-appellant Forage Genetics, Inc. converted from a C corporation to a domestic limited liability company called Forage Genetics International, LLC. Pursuant to Minn. Stat. §302.A.691, Forage Genetics International, LLC is for all purposes the same organization as Forage Genetics, Inc. Forage Genetics International, LLC is a wholly owned subsidiary of Land O'Lakes, Inc. No other corporation owns any stock or other interest in Forage Genetics International, LLC.

Monsanto and FGI are the owner and licensee, respectively, of the relevant patents for Roundup Ready alfalfa. Daniel Mederos and Mark Watte are farmers who made substantial investments in and grew Roundup Ready alfalfa.

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OPINIONS BELOW

The district court's opinion is unpublished and reproduced at Pet.App.60a-79a. The Ninth Circuit's original and amended opinions are reported at 541 F.3d 938, and 570 F.3d 1130, and reproduced at Pet.App.80a-103a and Pet.App.1a-26a, respectively.

JURISDICTION

The Ninth Circuit vacated its original opinion, entered an amended judgment, and denied a petition for rehearing and rehearing en banc on June 24, 2009. Pet.App.104a-07a. That order forbade any additional petitions for rehearing. *Id.* Justice Kennedy extended the time to file this petition until October 22, 2009. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The appendix reproduces the relevant constitutional amendment, statutes, and regulations.

STATEMENT OF THE CASE

This Court has emphasized that an injunction is "extraordinary and drastic remedy" that is "never awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008) (quotation marks omitted). Last Term, in *Winter v. NRDC*, 129 S. Ct. 365, 374-76 (2008), this Court held squarely that a NEPA plaintiff must establish that it is *likely* to be irreparably harmed to justify the extraordinary remedy of injunctive relief. Yet, the Ninth Circuit nonetheless persists in its view that NEPA plaintiffs are specially exempt from that requirement.

The Ninth Circuit upheld a nationwide injunction in this case by holding that the parties' dispute over the

potential for irreparable harm under a narrower, more limited injunction was immaterial at this stage of the proceedings—and did not warrant an evidentiary hearing—because the government would be focusing on the measures necessary to avert potential harm later when it prepared its environmental impact statement. Freed from the discipline imposed by the traditional likelihood-of-harm standard, the court of appeals approved an injunction that is so broad that it prohibits beneficial activities that pose no risk of harm whatsoever. If not reversed, the Ninth Circuit's holding threatens to make blanket injunctions all but automatic in NEPA cases arising in that circuit. As Judge Smith noted in dissent, "[t]here aren't many environmental cases that don't fit into the majority's newly-created exemption." Pet.App.26a (Smith, J., dissenting). Review by this Court is warranted.

BACKGROUND

The possibility of cross-pollination among nearby fields planted with different varieties of the same crop is an issue as old as agriculture, which farmers have always managed with locally-negotiated stewardship measures such as isolation distances. Pet.App.255a-64a, 212a-13a. Cross-pollination can occur only if both fields produce flowers simultaneously and pollen is transferred between them. When it does occur, cross-pollination affects only the fertilized flower, not the whole plant, and can be meaningful only where the flower is allowed to develop into a seed, and the seed is then harvested and sold. Pet.App.386a, 280a-83a, 178a-80a, 129a-30a. Where farmers purchasing seed are sensitive to varietal purity, cross-pollination can reduce the price of the seed.

This case is about a potential risk of cross-pollination among alfalfa fields. Alfalfa is a perennial crop with a three to five-year lifespan. Pet.App.126a. Each year, over 22 million acres of alfalfa are grown in the U.S. Pet.App.330a. Ninety-nine percent of that alfalfa is grown to produce hay, primarily used as feed for dairy operations. Pet.App.126a, 321a-22a, 330a. Alfalfa hay farmers have strong financial incentives to harvest their alfalfa before blooming, because flowering significantly decreases the nutritional (and hence financial) value of a crop. Pet.App.128a-29a. They do not introduce bees or other pollinators, and alfalfa does not shed pollen to the wind. Pet.App.129a-30a.

Less than 1% of alfalfa acreage is devoted to seed production, in just a handful of geographic areas. Pet.App.313a, 322a. Alfalfa seed farmers produce different varieties of conventional alfalfa seed. *See* Pet.App.148a, 216a. As with other crops, alfalfa seed farmers successfully utilize stewardship measures—including isolation distances between fields—when they wish to maintain varietal purity. *See* Pet.App.216a-17a, 212a-13a.

This case involves a particular variety of alfalfa created to address the problems caused by weeds in alfalfa fields, which substantially reduce the economic value of the crop to farmers and the nutritional value of feed for livestock. 126a-27a, 133a-34a. This alfalfa has been genetically engineered to be resistant to Roundup, a broad-spectrum agricultural herbicide that controls nearly every weed species in alfalfa crops. Pet.App.127a. Roundup's active ingredient is glyphosate, which the Environmental Protection Agency ("EPA") has found to be one of the most environmentally responsible herbicides available

commercially. Pet.App.195a-205a. The gene for glyphosate resistance occurs naturally, but not in alfalfa. Pet.App.43a. The alfalfa variety into which this gene has been introduced is known as Roundup Ready alfalfa ("RRA"). RRA is not harmed by Roundup, which kills weeds without affecting the crop. Pet.App.127a, 133a-34a. This is good for the farmer and the environment, because without RRA farmers use more toxic and expensive herbicides that must be applied more frequently. Pet.App. 121a-22a, 135a-36a, 239a. RRA is otherwise identical to conventional alfalfa. Pet.App.43a. It is undisputed that RRA is safe for food and animal feed. *Id.*

Since 1986, regulatory oversight for genetically-engineered crops has been governed by a "Coordinated Framework" involving three federal agencies: the Food and Drug Administration ("FDA"), EPA, and the U.S. Department of Agriculture ("USDA"). 51 Fed. Reg. 23,302, 23,302-09 (June 26, 1986). FDA is responsible for reviewing the safety of food/feed for humans and animals, and EPA examines potential health and environmental impacts of associated pesticide use under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §136 *et seq.* In addition, the Animal and Plant Health Inspection Service ("APHIS"), a division of USDA, examines whether the crop presents a "plant pest" risk under the Plant Protection Act ("PPA"), 7 U.S.C. §7701 *et seq.* 7 C.F.R. §340.6(d)(3).

After eight years of field testing, APHIS granted the petition of Monsanto and FGI (the owner and licensee of the relevant intellectual property) to grant RRA Nonregulated Status—an action commonly referred to as "deregulation"—allowing RRA to be

planted and sold commercially.[1] APHIS conducted its decision-making process subject to NEPA, which requires federal agencies to prepare an environmental impact statement ("EIS") for every "major Federal action[] significantly affecting the quality of the human environment." 42 U.S.C. §4332(2)(C). An agency is not required to prepare a full EIS if it determines—based on a shorter environmental assessment ("EA")—that the proposed action will not have a significant impact on the environment. 40 C.F.R. §§1508.9(a), 1508.13. When APHIS deregulated RRA, it simultaneously issued an EA and Finding of No Significant Impact ("FONSI").

Eight months later, a coalition of environmental organizations and individuals led by the Center for Food Safety brought suit challenging APHIS's decision.

PROCEEDINGS BELOW

1. *NEPA Merits Proceedings*

On February 13, 2007, the district court granted plaintiffs' motion for summary judgment on their NEPA-based claim that APHIS's EA was inadequate. The district court conceded that the case presented a "close question of first impression," but it ultimately concluded that APHIS had failed adequately to explain why the possibility of cross-pollination of conventional and organic alfalfa with RRA was not itself a significant harmful impact on the human environment,

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[1] This was the 67th petition APHIS has granted since 1995 to "deregulate" a genetically-engineered crop, and the 11th petition specifically for a glyphosate-resistant crop. *See* http://www.aphis.usda.gov/brs/not_reg.html.

and on that basis it ordered APHIS to prepare a full EIS. Pet.App.35a-45a, 51a-52a.

The district court's holding rested largely on the absence of any mandatory isolation distances for RRA seed crops or other stewardship measures to prevent cross-pollination in APHIS's unconditional grant of Nonregulated Status.[2] The district court emphasized that "once [RRA] is deregulated the government will not be able to impose isolation distances" and RRA planting will occur "without any geographic restrictions." Pet.App.36a, 52a.

2. *Remedial Proceedings*

APHIS submitted a proposed injunctive order that would have mandated precisely those sorts of stewardship measures, designed to prevent any non-trivial likelihood of cross-pollination during the agency's preparation of its EIS. These measures included isolation distances for RRA seed crops (1500 feet or 3 miles, depending on the type of bees used as pollinators) and hay crops (165 feet from any non-RRA alfalfa); a ban on adding pollinators to RRA hay crops; and requirements that all RRA hay crops be harvested before seed set, and harvested prior to 10% bloom if they are within 500 feet of non-RRA alfalfa. Pet.App.185a-86a. These measures were more stringent than the voluntary stewardship practices that RRA farmers had previously observed. For example, they would have increased isolation distances from 900 feet to 1500 feet when leafcutter bees are used as pollinators for seed crops (a 67% increase), and

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[2] The district court also concluded that APHIS did not take a "hard look" at the possibility that weeds might develop resistance to glyphosate, but the court did not rely on this rationale in fashioning injunctive relief. Pet.App.60a-79a.

to 3 miles when honey bees are used (a 1660% increase). Pet.App.140a, 162a-63a, 186a, 226a-28a.

APHIS explained that this proposal was based on its "many years of experience" regulating RRA, including 297 field trials over an 8-year period, as well as its experience with Roundup Ready corn, cotton, soybean, canola and sugarbeet crops. Pet.App.139a-40a. APHIS's expert declared that, with the agency's proposed stewardship measures in place, any potential for cross-pollination would be "minimal," "negligible"—and "under 0.1%." Pet.App.148a-50a, 162a-63a. APHIS also emphasized that the alternative—plaintiffs' proposed nationwide injunction on any further planting of RRA—would inflict unnecessary and substantial financial harm on approximately 3,000 RRA farmers located in 48 states. Pet.App.142a-47a.

The district court nonetheless rejected APHIS's measured approach. In its preliminary injunction order, issued on March 12, 2007, the court did not identify any likelihood of irreparable harm associated with RRA, and indeed did not analyze the traditional equitable factors for issuance of injunctive relief. Pet.App.54a-59a. Instead, the court applied the Ninth Circuit's "unusual circumstances" test: "In the run of the mill NEPA case, the contemplated project ... is simply delayed until the NEPA violation is cured.... [A]bsent unusual circumstances, an injunction is the appropriate remedy for a violation of NEPA's procedural requirements." Pet.App.55a (quotation marks and citations omitted). Because "[n]either the intervenors nor the government h[ad] identified any 'unusual circumstances,'" the court issued a nationwide injunction against all RRA planting after March 30, 2007. Pet.App.56a-58a.

Before entering permanent injunctive relief, the district court allowed the government and petitioners (which had intervened in the remedial proceedings) to "submit additional evidence or a further memorandum" and allowed plaintiffs to file a response to those submissions. Pet.App.58a. Petitioners proffered substantial additional evidence, including proposed testimony from four leading academic experts on alfalfa cultivation. Those experts explained that, with the government's proposed interim measures in place, the possibility of cross-pollination among hay crops—which account for 99% of alfalfa acreage—would be "negligible"; indeed, the risk was estimated at approximately 2.5 in one million (0.00025%). Pet.App.160a, 229a-35a, 280a-81a, 378-80a.[3] Even plaintiffs' own expert declarant admitted that hay crops do not present "any substantial risk of gene flow." Pet.App.359a. Petitioners' experts further explained that the possibility of cross-pollination from RRA to other alfalfa seed fields would be "extremely low"—*i.e.*, at or below 0.1% for seed fields stocked with leafcutter bees and less than 0.03% for those stocked

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[3] Several unlikely events would have to occur *seriatim* to permit hay-to-hay cross-pollination: (1) *both* the RRA and the conventional or organic hay field must be allowed to flower and go to seed, (2) the flowering of both fields must occur simultaneously, (3) bees must be present and actually pollinate the alfalfa crop, (4) any resulting seed must be permitted to mature, and (5) the seed must successfully germinate in the already established field. Pet.App.128a-30a, 178a-80a, 280a-83a. The chance of all of these events happening seriatim is infinitesimal. Pet.App.280a-83a. Since field testing began in 1998, and in the twenty-one months RRA was deregulated before the district court's injunction, there was *no* evidence of any cross-pollination from an RRA hay field to a conventional or organic hay field. Pet.App.29a, 408a-09a.

with honey bees. Pet.App.227a-29a, 234a-35a, 256a-57a.

Petitioners also submitted sample declarations of 17 farmers discussing the substantial losses they would suffer from a ban on RRA planting, and the report of an agricultural economist estimating those losses at more than $200 million. Pet.App.267a-69a. Plaintiffs' responsive submissions consisted largely of hearsay anecdotes of supposed cross-pollination.[4]

The district court refused petitioners' request for an evidentiary hearing and refused to rule on their evidentiary objections to plaintiffs' submissions. It merely held an "oral argument" on permanent relief. Pet.App.58a-59a. At that argument, the court made crystal clear its belief that it did not need to address the parties' dispute over the likelihood of irreparable harm:

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[4] For example, plaintiffs proffered the declarations of Jim Briggs and Ernest Johnson stating that they had heard representatives of Dairyland Seed Co. say that they had detected cross-pollination in Dairyland's seed fields. Pet.App.364a-67a, 372a. Plaintiffs also submitted a declaration from their counsel attaching a letter from the President of Cal/West to APHIS describing purported cross-pollination in its fields. Notably, even if there were any truth to that account—something petitioners were not permitted to test through cross-examination—those purported instances of cross-pollination involved exclusively seed-to-seed transmissions, appeared to have affected only 2-4% of the seed fields in the relevant geographic location, and in all but one case fell within a contractually contemplated 1% "tolerance" levels. Moreover, this alleged cross-pollination arose from planting conducted under stewardship techniques far less rigorous than APHIS's proposed mitigation measures. Pet.App.404a-07a. Indeed, the only cited instance of cross-pollination above the contractual 1% tolerance level involved a crop planted only 200 feet from an adjacent RRA seed field. *Id.*

> So I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it.... It just seems to me that ... I could be like a super environmental agency engaged in balancing all these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And number two, it isn't my job.... I should stop things in place until the Government has discharged its duty given to it by the right of Congress of the United States.

Pet.App.422a.

The district court reaffirmed that position in its Permanent Injunction Order. The court acknowledged that "intervenors have requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed." Pet.App.67a. But the court denied that request, reiterating its refusal "to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS...." Pet.App.68a. The court also reiterated its understanding that injunctive relief should issue "in the run of the mill NEPA case" and that "more liberal standards for granting an injunction'" apply in NEPA cases. Pet.App.55a, 65a-66a (citations omitted).

The district court refused to consider isolation distances of any length or any other stewardship measures proposed by APHIS. Pet.App.68a-70a; Pet.App.192a ("I am not going to get into isolation distances."). It entered a blanket nationwide injunction against any further planting of RRA without ever finding that irreparable harm would be "likely" with

the government's proposed mitigation measures in place. Pet.App.60a-79a. Indeed, the court "reject[ed]" out of hand the notion that interim measures allowing continued planting could be appropriate as a NEPA remedy, because APHIS should not be permitted to "skip the EIS process and decide without any public comment that deregulation with certain conditions [*i.e.* the proposed interim measures] is appropriate." Pet.App.69a; *see also* Pet.App.72a (concluding that, under Ninth Circuit law, "[a]llowing an expansion of the Roundup Ready alfalfa market pending the preparation of the EIS would be unprecedented").

To the extent the district court addressed the traditional equitable factors for the issuance of injunctive relief, it did so only cursorily and with an extraordinarily expansive concept of what constitutes irreparable harm. Without analyzing defendants' or intervenors' proposed expert testimony or allowing any cross examination of plaintiffs' contrary assertions, the district court held that any cross-pollination between RRA and organic or conventional alfalfa would constitute "irreparable harm" because "[t]he contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa." Pet.App.71a.[5] And, based on (i) plaintiffs' allegations that some "contamination has occurred" in certain seed crops under conditions "similar to" those proposed by APHIS, (ii) the remote, theoretical possibility that extreme weather conditions—such as months of continuous rain—might

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[5] *But see* Pet.App.181a-83a, 285a-87a, 410a-11a (explaining that the purported "contamination" could be avoided through inexpensive genetic tests and could be remedied with commonly used agricultural methods for ensuring varietal purity of seed crops).

permit hay-to-hay cross-pollination, and (iii) skepticism that APHIS has sufficient resources to ensure compliance with its proposed stewardship measures, the district court concluded that "plaintiffs h[ad] *sufficiently* established irreparable injury." Pet.App.71a (emphasis added).[6] At that time, the Ninth Circuit required only proof of "a 'possibility' [rather than a likelihood] of irreparable harm." *Winter*, 129 S. Ct. at 374-76; *accord Or. Natural Res. Council Fund v. Goodman*, 505 F.3d 884, 898 (9th Cir. 2007).

3. ***Ninth Circuit Opinion—as originally issued***

The Ninth Circuit affirmed the district court's judgment. It recognized that the district court did not conduct an evidentiary hearing, and that "generally, a district court must hold an evidentiary hearing" when material facts are in dispute. Pet.App.95a. The court also acknowledged that "[t]he parties' experts disagreed over virtually every factual issue relating to possible environmental harm, including the likelihood of genetic contamination." Pet.App.87a (quotation marks omitted). But it nonetheless approved the district court's holding that petitioners "had [not] established any material issues of fact" necessitating a hearing, because "the disputed matters [were] issues more properly addressed by the agency in the preparation of an EIS" and there was no reason for the district court to "duplicate the [agency's] efforts." Pet.App.95a-96a. (citing *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 831 (9th Cir. 2002)). The court also

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6 The district court derided the government's representation that it would enforce its proposed stewardship measures: "[H]aving the authority and effectively using the authority are two different matters: the government has the authority to enforce the immigration laws, but unlawful entry into the United States still occurs." Pet.App.70a.

rationalized that a NEPA-based injunction "has a more limited purpose and duration" and thus is "not a typical permanent injunction, which is of indefinite duration." Pet.App.95a-96a.

Despite the lack of an evidentiary hearing, the Ninth Circuit reviewed the "factual findings" of the district court only for clear error, and found the district court's "conclusion" that irreparable harm was "sufficiently likely" not clearly erroneous. Pet.App.91a-92a. Like the district court's opinion, the Ninth Circuit's original opinion was issued before *Winter*, when Ninth Circuit law counted a "mere possibility" of irreparable harm sufficient to support injunctive relief.

Judge Smith dissented. He objected that, "[i]nstead of giving deference to the agency's expertise, the majority gives deference to the district court, despite its wholesale rejection of the agency's proposal for an injunction and its failure to hold an evidentiary hearing." Pet.App.102a. He viewed the absence of an evidentiary hearing as a "critical failure ... [that] deprived the parties of important procedural right[]," Pet.App.100a, and threatens the rights of others in future cases: "There aren't many environmental cases that don't fit into the majority's newly-created exemption." Pet.App.102a. "Based on [the] record" in this case, moreover, Judge Smith had "serious concerns about the scope of the injunction entered by the district court." Pet.App.102a-03a. "At best," he believed "the record reflect[ed] sparse evidence of hay-to-hay gene transmission of RRA alfalfa in some areas of the country under certain planting conditions," and he saw "no good evidence of hay-to-seed or seed-to-seed gene transmission" and thus no basis for the district court's "nationwide injunction on the planting of Roundup

Ready alfalfa while APHIS completes an EIS," which had "severe economic consequences." *Id.*

4. ***Amended Opinion***

In response to the intervenors' rehearing petition and supplemental filings, which highlighted this Court's intervening decision in *Winter*, the Ninth Circuit vacated its original opinion and issued an amended opinion on denial of rehearing. Pet.App.107a. That amended opinion added as a new rationale a contention that the district court actually did hold an evidentiary hearing because it permitted Mark McCaslin, president of petitioner FGI, to address the court with unsworn statements from counsel's table at the oral argument on plaintiffs' preliminary injunction motion. Pet.App.23a. But the amended opinion contradicts itself on that score, as it adheres to the court of appeals' original statements that the "district court here correctly denied a hearing," and that "[w]hat the district court did not do was to hold an additional evidentiary hearing to resolve the very disputes over the risk of environmental harm that APHIS would have to consider in the EIS." Pet.App.19a-20a. Judge Smith observed in dissent that "the record does not confirm [the majority's revisionist] description," as the oral arguments on which the majority relied "f[ell] far short of the standards we have articulated for [an evidentiary] hearing...." Pet.App.23a.

The amended opinion does not discuss *Winter*'s holding that the traditional equitable standards, including a finding of likely irreparable harm, must be satisfied to justify injunctive relief for a NEPA violation. Instead, the Ninth Circuit merely added a cite to *Winter* as support for a preexisting sentence approving the district court's conclusion that

irreparable harm was "sufficiently likely" in this case. *Compare* Pet.App.13a *with* Pet.App.91a.

Although the district court ordered APHIS to prepare an EIS 32 months ago, APHIS has not yet published a draft EIS, the district court's nationwide injunction against any planting of RRA, *even for hay*, remains in place, and the harm to alfalfa growers continues.

REASONS FOR GRANTING THE WRIT

This Court has held time and again that federal courts considering injunctive relief to remedy violations of environmental statutes must apply the traditional four-factor equitable test, absent clear contrary direction from Congress. *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982) (rejecting "'absolute statutory obligation'" to enjoin violations of environmental statutes) (citation omitted); *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542-45 (1987) (reversing Ninth Circuit presumption of irreparable harm in environmental cases). Last Term, in *Winter*, this Court made clear that the traditional four-factor test applies equally to injunctions sought in the NEPA context, and held specifically that a district court may not enter an injunction for a NEPA violation broader than necessary to prevent a likelihood of irreparable harm pending the government's preparation of an EIS. *Winter*, 129 S. Ct. at 374-76.

Despite those on-point holdings, the Ninth Circuit has now invented a new special rule that will effectively permit district courts once again to *presume* irreparable harm in NEPA cases. The Ninth Circuit affirmed the district court's blanket nationwide injunction against planting RRA despite a federal agency's expert view that a more limited injunction

would suffice to prevent any significant cross-pollination—and, indeed, affirmed the district court's denial of petitioners' request for an evidentiary hearing on that issue—because it agreed with the district court that the likelihood of irreparable harm is simply immaterial in the NEPA context. In the Ninth Circuit's view, it is a waste of judicial resources to spend time determining whether a more limited injunction would suffice to prevent irreparable harm, when the agency will eventually have to analyze appropriate risk-avoidance measures in the course of its EIS process anyway. That reasoning cannot be reconciled with this Court's precedents and impermissibly enlarges both the equitable power of federal courts and the scope of NEPA.

The Ninth Circuit also rationalized that it could refuse petitioners' request for an evidentiary hearing because a permanent injunction in the NEPA context is really just an "interim measure[]," lasting only until the new EIS issues. Pet.App.17a-20a. But a *preliminary* injunction is also by definition "interim" in nature, and *Winter* (like prior decisions of this Court) admonishes that a "preliminary injunction is an extraordinary remedy never awarded as of right," and that district courts must make factual findings under the traditional four-factor test even for *preliminary* injunctions. 129 S. Ct. at 374-76. Moreover, the deprivation of an evidentiary hearing in the face of genuine disputes over material facts conflicts with centuries of common law and the holdings of numerous other courts of appeals.

To be sure, the Ninth Circuit also affirmed the district court's "conclu[sion] that plaintiffs had established that genetic contamination was *sufficiently likely* to occur so as to warrant broad injunctive relief."

Pet.App.13a (emphasis added). But far from rescuing the court of appeals' opinion, if that is viewed as an alternative holding it introduces distinct and equally fundamental errors. At the time of the district court's ruling, Ninth Circuit case law deemed *sufficient* a showing that irreparable harm was "possible." *Winter*, 129 S. Ct. at 374-75; *Goodman*, 505 F.3d at 898. After this Court repudiated that formulation in *Winter*, the Ninth Circuit at a minimum should have vacated the district court's judgment in this case and instructed the court on remand to determine the breadth of injunction necessary to prevent *likely* irreparable harm. The Ninth Circuit refused to do that. Its affirmation of an injunction that was based on the district court's concern over the mere possibility of cross-pollination with some conventional or organic crops—a monetary injury that is manifestly reparable in any event—cannot be reconciled with *Winter*'s holding that irreparable harm must be likely. 129 S. Ct. at 374-75. For at least the 99% of alfalfa that is planted for hay, cross-pollination is almost a scientific impossibility. And for the remaining 1% that is planted for seed, it would still be highly *un*likely with the APHIS's stewardship measures in place.

If permitted to stand, the Ninth Circuit's decision threatens to effectively nullify this Court's holdings in *Winter*, *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), and *Amoco*, make broad injunctive relief all but automatic (*i.e.*, "as of right") whenever a district court finds a NEPA violation in the Ninth Circuit, and impermissibly expand the scope of NEPA. Unjustified nationwide injunctions blessed by the courts in that circuit will pose a significant threat to important government programs and will inflict enormous financial losses on private businesses and individuals

that have reasonably relied on the government's regulatory approvals. This Court's review is warranted.

I. THE NINTH CIRCUIT'S DENIAL OF AN EVIDENTIARY HEARING ON THE GROUND THAT THE LIKELIHOOD OF IRREPARABLE HARM IS IMMATERIAL TO THE ISSUANCE OF A NEPA INJUNCTION WARRANTS THIS COURT'S REVIEW

The district court believed that it was not required to grapple with the likelihood of irreparable harm before entering a nationwide injunction against any further planting of RRA. Judge Breyer insisted "I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it" and refused to "conduct ... the very same scientific inquiry [he had] ordered APHIS to do." Pet.App.68a, 422a; *accord supra* at 9-11. As the United States observed below, "the court refused to make any findings regarding gene flow." Opening Brief of Federal Defendants-Appellants ("U.S. Br."), *Geertson*, at 27.

The Ninth Circuit approved of the district court's approach and adopted its holding. It acknowledged that, "generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed." Pet.App.17a. There was no waiver here, and the court of appeals recognized that the parties' experts disagreed vehemently over the likelihood of irreparable harm. Pet.App.9a. Yet the court of appeals affirmed the district court's denial of an

evidentiary hearing on the ground that no "material issues of fact ... were in dispute." Pet.App.17a-18a. In other words, according to the Ninth Circuit, the parties' disagreement over the likelihood of irreparable harm was not material to whether the injunction was justified.

Like the district court, the Ninth Circuit reasoned that judicial analysis of the relevant likelihoods would unnecessarily "duplicate APHIS's efforts" and "divert [APHIS's] resources." Pet.App.18a-19a. Indeed, the court of appeals characterized the necessity of engaging on the likelihood of irreparable harm—a quintessential precondition to issuing *any* injunction under traditional standards—as "the catch-22 situation." Pet.App.18a. The Ninth Circuit's approach views the agency's later EIS process as a *substitute* for application of the traditional equitable factors for injunctive relief by federal courts, reasoning that the district court need only "allow for a[n] [EIS] process to take place which will determine permanent measures." *Id.*

The Ninth Circuit drew that reasoning from its prior decision in *Idaho Watersheds*. *Id.* In that case, however, the court justified the denial of an evidentiary hearing on irreparable harm in part based on the district court's appropriate deference to the form of injunctive relief proposed by the government. *See Idaho Watersheds*, 307 F.3d at 830-31 (noting the circuit's historic "deference for factual and technical determinations implicating substantial agency expertise"). Whatever the merits of that decision, it does not justify a district court's refusal to engage on the likelihood of irreparable harm when it is *rejecting* the government's measured approach in favor of a nationwide blanket injunction. In this circumstance,

the Ninth Circuit's holding promotes a uniquely non-deferential form of judicial abstention, under which a federal court may, in supposed deference to an expert agency's future decision-making processes, issue an injunction that the agency considers to be overbroad and unnecessary.

The Ninth Circuit's approach conflicts directly with this Court's decisions in *Winter*, *eBay*, and *Amoco*. Those decisions make clear that courts should not carve out subject-matter exceptions to the "traditional four-factor framework that governs the award of injunctive relief," *eBay*, 547 U.S. at 394, and that the likelihood of irreparable harm—like all of the traditional equitable factors—must be analyzed by courts *before* injunctions issue. *See, e.g.*, *Winter*, 129 S. Ct. at 374-75; *eBay*, 547 U.S. at 391-94; *Amoco*, 480 U.S. at 542. In *Winter* and *Amoco*—as here—the defendant federal agency was proceeding to conduct additional, court-ordered environmental studies. *Winter*, 129 S. Ct. at 376, 381-82 & n.5; *Amoco*, 480 U.S. at 538-39. Despite those ongoing agency processes, this Court nonetheless examined the likelihood of irreparable harm *itself* without any suggestion that the upcoming agency processes rendered that issue immaterial. *Winter*, 129 S. Ct. at 375-76; *Amoco*, 480 U.S. at 544-45, (concluding such harm was "not at all probable").

By allowing a district court to order broad injunctive relief without first finding the requisite irreparable harm, the Ninth Circuit has effectively resurrected the presumption of irreparable harm that this Court repudiated in *Amoco*. 480 U.S. at 544-45; *see also* U.S. Br. at 4 ("The district court issued this blanket injunction by presuming irreparable harm ...."). Although the Ninth Circuit disclaims endorsing any such presumption, Pet.App.13a, allowing district

courts to issue injunctions without adjudicating the likelihood of irreparable harm amounts to the same thing. *See* Reply Brief of Federal Defendants-Appellants, *Geertson*, at 14 (noting that the "presumption of irreparable harm applied by the district court [and affirmed by the Ninth Circuit] is problematic because it caused the court to issue an overbroad injunction").

The Ninth Circuit's approach also conflicts squarely with that of the Second Circuit, which reversed a district court's refusal to convene an evidentiary hearing to adjudicate the issue of irreparable harm in a NEPA case. *See Huntington v. Marsh*, 884 F.2d 648, 654 (2d Cir. 1989) (observing that "no consideration was given" by the district court as to "whether plaintiff has met its burden to establish some actual or threatened injury"), *cert. denied*, 494 U.S. 1004 (1990). Even though—as in this case—the agency was in the process of preparing an EIS, the Second Circuit reversed and remanded so that the *district court* would adjudicate the likelihood of irreparable harm at an evidentiary hearing. *Id.* at 651, 653-54. In contrast to the Ninth Circuit, the Second Circuit held that "a threat of irreparable injury *must be proved, not assumed*, and *may not be postulated eo ipso* on the basis of procedural violations of NEPA." *Id.* at 653 (emphasis added).

The Ninth Circuit's decision also impermissibly enlarges the scope of NEPA. NEPA is, of course, a procedural statute, which mandates no "particular results." *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350, 353 n.16 (1989). Moreover, an agency's compliance with NEPA is reviewed under the APA, which does not mandate injunctive relief when a violation is found. *See* 5 U.S.C. §703 (providing

that either declaratory or injunctive relief may be appropriate); *see also Winter*, 129 S. Ct. at 381 (observing that federal courts have "many remedial tools at [their] disposal, including declaratory relief or an injunction tailored to the preparation of an EIS rather than the [challenged government activity] in the interim"). The Ninth Circuit's decision nevertheless permits a NEPA plaintiff to obtain an injunction—indeed, as in this case, a *permanent* injunction—against agency action without even satisfying the traditional elements of injunctive relief.

Beyond the conflicts it has created with decisions of this Court and the Second Circuit, the Ninth Circuit's decision warrants review for practical reasons. As the United States has recognized, "the proper standard for evaluating requests for injunctive relief in connection with violations of [NEPA] involves an important question of federal law." Federal Opposition to Certiorari, *Huntington* (No. 89-781), *available at* http://www.usdoj.gov/osg/briefs/1989/sg890315.txt. The government lost 288 NEPA cases from 2006 to 2008 alone,[7] and as the remedy for a NEPA violation almost invariably involves additional environmental study by the agency, the Ninth Circuit's revitalized presumption of irreparable harm threatens to apply in virtually all of the NEPA cases arising in that circuit. *See* Pet.App.26a (Smith, J., dissenting) ("There aren't many environmental cases that don't fit into the majority's newly-created exemption."). The Ninth Circuit's effective revival of its *pre-Amoco*

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[7] *See* NEPA Litigation Surveys, *available at* http://ceq.hss.doe.gov/nepa/NEPA2006LitigationSurvey.pdf; http://ceq.hss.doe.gov/nepa/NEPA2007LitigationSurvey.pdf; http://ceq.hss.doe.gov/nepa/NEPA2008LitigationSurvey.pdf.

presumption thus once again "presents a serious and continuing problem for countless federal projects and programs...." Federal Petition for Certiorari, *Amoco* (No. 85-1406), *available at* http://www.usdoj.gov/osg/briefs/1985/sg850057.txt. It similarly threatens to inflict billions of dollars of unjustified economic injury—indeed more than $200 million in this case alone—on businesses and individuals who have made substantial investments in reliance on the government's regulatory approvals. *See also* U.S. Br. at 41 ("RRA growers had made substantial investments in RRA by the time Geertson finally sought injunctive relief ....").

II. THE NINTH CIRCUIT'S DENIAL OF AN EVIDENTIARY HEARING ON THE GROUND THAT NEPA INJUNCTIONS ARE MERELY "TEMPORARY" WARRANTS THIS COURT'S REVIEW

In addition to its view that the likelihood of irreparable harm is immaterial to injunctions issued in NEPA cases, the Ninth Circuit indicated that an evidentiary hearing was unnecessary here because a permanent injunction entered pending the preparation of an EIS is inherently "temporary." If the Ninth Circuit meant that proof of a likelihood of irreparable harm is immaterial where the proposed injunction is merely temporary, its decision runs headlong into this Court's precedents (including *Winter*) recognizing that a preliminary injunction is itself an "extraordinary remedy" that requires (among other things) proof of a likelihood of irreparable harm before it may be issued. 129 S. Ct. at 374-76. If the Ninth Circuit instead meant that district courts may deny evidentiary hearings when faced with genuine disputes over facts material

to the issuance of permanent injunctions, its decision runs headlong into centuries of common law, basic concepts of due process, and the Federal Rules of Civil Procedure—and conflicts with the decisions of virtually every court of appeals that has addressed the issue.[8]

For nearly a millennium, Anglo-American jurisprudence has resolved material factual disputes in the same manner: trial-based, adversarial proceedings. *See, e.g.*, 3 William Blackstone, *Commentaries on the Laws of England* 349 (1768) (tracing trials back "so early as the laws of king Ethelred [king of England from 978-1016]" and observing "trial[s] ... ha[ve] been used time out of mind in this nation, and seem[] to have been co-eval with the first civil government thereof"); *Greene v. McElroy*, 360 U.S. 474, 496-97 & n.25 (1959) (observing that "[c]ertain principles," such as live testimony and cross examination, "have remained relatively immutable in our jurisprudence" and tracing protections back "more than two thousand years" to Roman law).

The ancient principle that material factual disputes must be resolved through trial is, indeed, core to our notions of due process. This Court has observed that, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses." *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970);

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[8] Beyond refusing an evidentiary hearing, the district court's review of the parties' paper submissions lacked any semblance of procedural integrity. Among other things, the court relied on plaintiffs' anecdotal tales of alleged RRA "contamination" without pausing to consider petitioners' motion to strike that material on hearsay and other evidentiary grounds, much less subjecting those accounts to the crucible of cross-examination. *See supra* at 9.

see also Ingraham v. Wright, 430 U.S. 651, 672-73 (1977) ("[T]he Fifth Amendment ... was intended to give Americans at least the protection against governmental power that they had enjoyed as Englishmen against the power of the Crown."); *Hamdi v. Rumsfeld*, 542 U.S. 507, 556 (2004) (Scalia, J., dissenting) ("The gist of the Due Process Clause, as understood at the founding and since, was to force the Government to follow those common-law procedures traditionally deemed necessary ....").

The need to convene evidentiary hearings to resolve material factual disputes is also implicit in the Federal Rules of Civil Procedure, which provide only two mechanisms by which a full trial to verdict can be avoided and judgment nevertheless entered—directed verdicts and summary judgments. *See* Fed. R. Civ. P. 50, 56. The standard for both procedures is the same: there must "be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 250 (1986). Outside of these two procedures, district courts must resolve factual disputes the way common law courts always have, through live adversarial proceedings.

In the leading modern case, *United States v. Microsoft*, the D.C. Circuit, sitting *en banc*, unanimously reversed a district court's imposition of an injunction without an evidentiary hearing. 253 F.3d 34, 101 (D.C. Cir.), *cert. denied*, 534 U.S. 952 (2001). The D.C. Circuit grounded its analysis on the "cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings," and its recognition that "[a]ny other course would be contrary 'to the spirit which imbues our judicial tribunals prohibiting decision without hearing.'" *Id.* (quoting *Sims v. Greene*, 161

F.2d 87, 88 (3d Cir. 1947)). The D.C. Circuit recognized, moreover, that "[a] party has the right to judicial resolution of disputed facts not just as to the liability phase, but also as to appropriate relief." *Id.* Following the Federal Rules and the common law's well-established procedures, the court held that "[o]ther than a temporary restraining order, *no injunctive relief may be entered without a hearing.*" *Id.* (emphasis added). The only exception it acknowledged was for temporary restraining orders, which generally are limited to no more than 10 days. *Id.* (citing Fed. R. Civ. P. 65).

Consistent with *Microsoft*, it is settled law in virtually every circuit that has considered this issue that a district court considering entry of an injunction must conduct an evidentiary hearing upon request if there are any material facts in dispute. *See Four Seasons Hotels & Resorts, B.V. v. Consorcio Barr, S.A.*, 320 F.3d 1205, 1211 (11th Cir. 2003); *In re Rationis Enters., Inc. of Panama*, 261 F.3d 264, 269 (2d Cir. 2001); *Microsoft*, 253 F.3d at 101-02; *Prof'l Plan Examiners of N.J., Inc. v. Lefante*, 750 F.2d 282, 288 (3d Cir. 1984); *United States v. McGee*, 714 F.2d 607, 613 (6th Cir. 1983).

The Ninth Circuit also "generally" adheres to this rule. Pet.App.17a; *see also, e.g., Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988). But it distinguishes cases arising under NEPA from the "'normal injunctive setting'" because, in contrast to "typical" injunctions of "indefinite duration," NEPA-based injunctions are temporary. Pet.App.18a. Contrary to the Ninth Circuit's reasoning, a party's common law and due process right to an evidentiary hearing on the propriety and scope of injunctive relief does not depend on the projected duration of the

injunction. A preliminary injunction is by its nature "temporary." Yet courts have recognized the right to an evidentiary hearing equally in the context of preliminary injunctions. *See Four Seasons Hotels*, 320 F.3d at 1211; *In re Rationis Enters.*, 261 F.3d at 269; *Microsoft*, 253 F.3d at 101-02; *Lefante*, 750 F.2d at 288; *see also* 13 James Wm. Moore, *Moore's Federal Practice* §65.21[4] (3d ed. 2009) ("A hearing on the merits of the preliminary injunction is thus usually required only when a dispute exists between the parties as to the material facts."). *But see Campbell Soup Co. v. Giles*, 47 F.3d 467, 470 (1st Cir. 1995) (rejecting "'categorical rules'" of other circuits and instead "'balancing between speed and practicality versus accuracy and fairness'" (citation omitted)). Moreover, all permanent injunctions are inherently "temporary" in the sense that they will expire when either the violation is remedied or the controversy is mooted. *See, e.g., Bd. of Educ. of Okla. City Pub. Schs. v. Dowell*, 498 U.S. 237, 248 (1991) (holding that injunctions, even for constitutional violations, "are not intended to operate in perpetuity"). Indeed, federal courts are often *supposed to facilitate* the expiration of their injunctions—despite their styling as being "permanent." *See, e.g., Horne v. Flores*, 129 S. Ct. 2579, 2595-96 (2009) (holding that federal courts have an obligation to see that authority is "'returned *promptly* to the State and its officials,'" and that once a violation has been remedied, "continued enforcement of the order is not only unnecessary, *but improper*") (citation omitted) (emphasis added)). It is thus hardly exceptional that NEPA-based "permanent injunctions" are likely—and supposed—to expire at some point.

By nonetheless inventing a special NEPA-only exception to the general evidentiary hearing

requirement, the Ninth Circuit 's decision directly and specifically conflicts with the Second Circuit's decisions in *Huntingon*, which vacated *NEPA-based* injunctions issued without evidentiary hearings on irreparable harm and mandated such hearings on remand. *Huntington*, 884 F.2d at 649, 653-54. More generally, the Ninth Circuit's holding splits it from the D.C. Circuit, which excepts only TROs from the evidentiary hearing requirement, and conflicts with the views of many other courts of appeals, which have long recognized the right to evidentiary hearings without concern for the likely duration of the injunction. *See supra* at 26-27; 11A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* §2949 (2d ed. 1995 & Supp. 2009) ("Although the Ninth Circuit permits the trial court to exercise discretion to decline to hear testimony even when the facts are controverted, most courts hold that when the written evidence reveals a factual dispute, an evidentiary hearing must be provided to any party who requests one." (footnotes omitted)).

The Ninth Circuit's refusal in NEPA cases to enforce such a basic hallmark of due process, in conflict with centuries of common law and the decisions of numerous other courts of appeals, warrants this Court's review.

III. THE NINTH CIRCUIT'S AFFIRMANCE OF AN INJUNCTION BASED ON THE MERE POSSIBILITY OF REPARABLE HARM WARRANTS THIS COURT'S REVIEW

To the extent that the Ninth Circuit addressed the question of irreparable harm on the merits, it affirmed the injunction despite the district court's application of

the flawed *possibility*-of-harm test that this Court repudiated in *Winter* and despite the absence of any showing that the feared harm would be irreparable. The Ninth Circuit's decision thus flunks both components of *Winter*'s holding that a "plaintiff ... must establish ... that he is *likely* to suffer *irreparable* harm." 129 S. Ct. at 374 (emphasis added). Although petitioners believe that the Ninth Circuit's broad holdings merit plenary review, its specific errors in this case are also sufficiently egregious to warrant summary reversal.

Applying the Ninth Circuit's then-prevailing test, the district court never required plaintiffs to prove that irreparable harm was *likely*. *See* Pet.App.60a-79a. Indeed, the district court twice relied upon the mere "*potential*" for irreparable harm, holding, for example, that the financial harm to farmers did "not outweigh the *potential* for irreparable harm." Pet.App.72a (emphasis added); *see also* Pet.App.75a. But it never found a "likelihood" or "certainty" of such harm, only "potential"—*i.e. possible*—harm. The district court had no reason to go farther, because at the time the Ninth Circuit required only a possibility of harm. *Winter*, 129 S. Ct. at 374-75.

Winter was decided, and brought to the Ninth Circuit's attention, while this case was pending on rehearing. The Ninth Circuit should, at a minimum, have vacated the district court's judgment in light of *Winter* and remanded this case with directions for the district court to assess whether plaintiffs proved that irreparable harm was likely. In particular, it should have required the district court to engage in the sort of narrow tailoring that *Winter* demands and to evaluate whether there would be a likelihood of irreparable harm with APHIS's proposed stewardship measures in

place. *See Winter*, 129 S. Ct. at 376 (faulting district court's failure to evaluate "the likelihood of irreparable harm in light of the four restrictions not challenged by the Navy," including a "12-mile exclusion zone" roughly akin to an agricultural isolation distance). It refused to do that. The Ninth Circuit's only response to this argument on rehearing was disingenuous: it simply added *Winter* as a citation to a sentence it had *already written pre-Winter* that irreparable harm was "sufficiently likely." *Compare* Pet.App.13a *with* Pet.App.91a. But what was "sufficiently likely" before and after *Winter* in the Ninth Circuit are two very different things—hence this Court's grant of certiorari and reversal on that precise point. *Winter*, 129 S. Ct. at 375-76. [9]

The difference was dispositive here, and the Ninth Circuit's error if anything is even more egregious than in *Winter*. There was no evidence at all, admissible or inadmissible, that there has ever been *any* cross-pollination from RRA within this country's more than 22 million acres of hay crops, and the uncontradicted evidence shows that, with use of APHIS's stewardship measures, that risk would be around 2.5 in one million. Pet.App.277a-81a, 408a-09a. Ninety-nine percent of alfalfa grown in this country is grown for hay. The court of appeals repeated the district court's

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[9] It is clear from the record in this case that the district court's injunction could not have been justified under the likelihood-of-irreparable harm standard that this Court articulated in *Winter*. But even if there were any doubt about that, the Ninth Circuit still plainly erred in not remanding the case to the district court to apply the proper standard. *See Winter*, 129 S. Ct. at 376 (vacating injunction even though "[i]t is not clear that articulating the incorrect standard affected the Ninth Circuit's analysis of irreparable harm").

speculation that "weather conditions *could* [cause cross-pollination from hay crops by] prevent[ing] farmers from harvesting hay before 10% bloom," Pet.App.14a (emphasis added). But hypothesizing what "could" occur is plainly the wrong inquiry under *Winter*.

Even as to the rare 1% of alfalfa that is planted for seed, the evidence showed that, with use of APHIS's stewardship measures, the probability of cross-pollination would be less than 0.1%—very far from a likelihood. *Supra* at 7-9. Moreover, growers of different varieties of alfalfa seeds have successfully used far shorter isolation distances to coexist for decades. Pet.App.382a-83a (noting certified seed growers use 165-330 feet isolation distances between varieties); Pet.App.216a; *see also Winter*, 129 S. Ct. at 376 ("find[ing] it pertinent that this is not a case in which the defendant is conducting a new type of activity with completely unknown effects on the environment").

Beyond rejecting the government's proposal, the district court made no effort itself to narrowly tailor the injunction. It enjoined *all* planting of RRA, for hay or seed, even in locations where there is no organic or conventional alfalfa for hundreds of miles. *See, e.g.*, Pet.App.221a ("[W]e are completely isolated from any conventional or organic seed production—the closest conventional seed operation is more than 300 miles away ...."); Pet.App.208a ("[T]here are only nine growers of organic hay in the entire state [of Nevada] and they are all in isolated areas ...."). Had the court made any effort at narrow tailoring, it would have found that there are isolation distances at which the risk of cross-pollination is no longer even theoretically possible—let alone "likely."

The court of appeals' affirmance that the feared harm from cross-pollination would be "irreparable" is also completely divorced from record. As an initial matter, it is unclear what harm the lower courts relied upon. The Ninth Circuit's opinion notes the district court's reference to the "potential[]" of RRA to "eliminate the availability of non-genetically engineered alfalfa" in discussing the public interest. Pet.App.14a-15a. And the district court does seem to have relied in part upon "the potential of eliminating the availability of a non-genetically engineered crop." Pet.App.75a. That concern is preposterous and has no support in the record. The likelihood of such a science-fiction scenario unfolding—and that such hegemony could be established while APHIS is preparing the EIS—is *zero*. Since the dawn of agriculture, hundreds of different varieties of common crops have been cultivated without any one of them displacing all the others. Moreover, the Roundup Ready gene confers no selective advantage other than glyphosate resistance. Pet.App.398a. Because most farmers do not use glyphosate (Pet.App.122a, 240a) and no organic farmers do so (Pet.App.263a-64a, 401a), the suggestion that cross-pollination from RRA may eliminate the availability of all other varieties of alfalfa is entirely fanciful. Pet.App.387a-88a, 397a-98a, 413a.

The lower courts' opinions also indicate that *any* cross-pollination will inflict irreparable harm on affected conventional or organic farmers. The district court, for example, stated that cross-pollination from RRA constitutes "irreparable harm" because "[t]he contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa." Pet.App.71a; *see also* Pet.App.44a ("For those farmers who choose to grow non-

genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa ...."). The Ninth Circuit similarly relied upon hearsay evidence that individual instances of "genetic contamination" "had already occurred" and were "sufficiently likely to occur so as to warrant broad injunctive relief." Pet.App.13a.

The notion that *any* cross-pollination within *any* individual farmer's crops would constitute irreparable harm exemplifies precisely the same zero-tolerance approach the Ninth Circuit took in *Winter*, only to be reversed by this Court. *See NRDC v. Winter*, 518 F.3d 658, 697 (9th Cir.) (rejecting Navy's argument that "NRDC was required to demonstrate the possibility of irreparable injury at the *species* or *stock*-level" (emphasis added)), *rev'd*, 129 S. Ct. 365 (2008). And it creates a direct split with the D.C. and First Circuits, which have held that "the loss of only one [animal] is [not] sufficient injury to warrant [injunctive relief]" and a plaintiff instead must demonstrate "irretrievabl[e] damage [to] the species." *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975) (refusing to "equate the death of a small percentage of a reasonably abundant game species with *irreparable* injury"); *accord Water Keeper Alliance v. U.S. DoD*, 271 F.3d 21, 34 (1st Cir. 2001) (holding death of a "'single member of an endangered species'" was "insufficient" absent showing of how "probable deaths ... may impact the species" (citation omitted)). Isolated instances of cross-pollination would not constitute irreparable harm to alfalfa as a species, and the D.C. and First Circuits thus would have reversed the injunction entered below. The United States identified these same circuit splits as necessitating this Court's

review in *Winter*. *See* Petition for Certiorari, *Winter* (No. 07-1239), at 27-28. Moreover, to the extent the Ninth Circuit was concerned for the welfare of organic farmers, all existing standards for organic certification, here and abroad, permit crops to be sold as "organic" despite low levels of cross-pollination. Pet.App.182a-83a, 263a-64a. And even if those standards were violated, the resulting harm would be economic and, to the extent permitted by state law, reparable—not, as the Ninth Circuit seemed to believe, a catastrophic existential threat.

The Ninth Circuit's brazen refusal to apply *Winter* in this case unfortunately is not unique. *See, e.g.*, *Nelson v. NASA*, 568 F.3d 1028, 1050 (9th Cir. 2009) (Kleinfeld, J., dissenting) ("The panel's injunction failed to consider this public interest factor, contrary to the Supreme Court's recent admonition [in *Winter*]."); *Greater Yellowstone Coal. v. Timchak*, 323 Fed. Appx. 512, 513-14 & n.1 (9th Cir. 2009) (despite *Winter*, granting temporary stay of activity because of "possibility that the district court may conclude on remand that irreparable harm *might* occur" (emphasis added)). Such outright defiance of this Court's precedent calls for a prompt response by this Court. *See, e.g.*, *Nelson v. United States*, 129 S. Ct. 890, 891-92 (2009) (per curiam) (reversing where court of appeals failed to give effect to Court's "recent precedents"); *Spears v. United States*, 129 S. Ct. 840, 842-46 (2009) (per curiam) (same); *Allen v. Siebert*, 128 S. Ct. 2, 3-5 (2007) (per curiam) (same). Indeed, the Ninth Circuit's track record on this issue coupled with the important and recurring nature of the question underscore the need for the Court's review.

CONCLUSION

The petition for certiorari should be granted, and the case should be heard on the merits or summarily reversed.

Respectfully submitted,

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OCTOBER 22, 2009

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEERTSON SEED FARMS, an Oregon business; Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp.,

v.

Mike JOHANNS, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants.

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors,

and

Monsanto Company, Defendant-Intervenor-Appellant.

Geertson Seed Farms, an Oregon business; Trask Family Seeds, a South Dakato business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond

Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp., Plaintiffs-Appellees,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants,

Monsanto Company, Defendant-Intervenor,

and

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors-Appellants.

Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp.; Geertson Seed Farms, an Oregon business, Plaintiffs-Appellees,

and

Geertson Seed Farms, an Oregon Corp., Plaintiff,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the United States Environmental Protection Agency, Defendants-Appellants

and

Monsanto Company; Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors.

Nos. 07-16458, 07-16492, 07-16725.

Argued and Submitted June 10, 2008.
Filed June 24, 2009.

570 F.3d 1130

Before: MARY M. SCHROEDER and N. RANDY SMITH, Circuit Judges, and VALERIE FAIRBANK,* District Judge.

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* The Honorable Valerie Fairbank, United States District Judge for the Central District of California, sitting by designation.

Opinion by Judge SCHROEDER; Dissent for Judge N. SMITH.

ORDER AND AMENDED OPINION

[Order Denying Rehearing
Reproduced at Pet. App. 104a-107a]

OPINION

SCHROEDER, Circuit Judge:

The Monsanto Company ("Monsanto") is a large-scale manufacturer of chemical products, including herbicides and pesticides. In the 1990s it began developing a variety of alfalfa that would be resistant to one of its leading herbicides. The United States Department of Agriculture, through the Animal and Plant Health Inspection Service ("APHIS"), approved the genetically modified alfalfa in 2005.

This is an appeal from an injunction entered by the district court enjoining future planting of Monsanto alfalfa, called "Roundup Ready alfalfa," pending the preparation by APHIS of an environmental impact statement ("EIS"). The injunction was sought by plaintiffs Geertson Seed Farms and Trask Family Seeds, conventional alfalfa-seed farms, together with environmental groups, because they fear cross-pollination of the new variety with other alfalfa, thereby possibly causing conventional alfalfa to disappear. Monsanto and its licensee, Forage Genetics, Inc. ("Forage Genetics"), intervened on the side of the government defendants. Monsanto, Forage Genetics, and the government pursue this appeal.

There are no issues of law and we therefore review for abuse of discretion. *See Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 823 (9th Cir.2002). We affirm because the district court did not abuse its discretion in entering the injunction after holding one hearing on the nature of the violation of the National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. § 4332(C), and two hearings on the scope of injunctive relief, as well as reviewing extensive documentary submissions relating to an appropriate remedy. The injunction is limited in duration to the time necessary to complete the EIS. The existence of the NEPA violation is not disputed on appeal.

Background

Roundup Ready alfalfa is an alfalfa crop that was genetically engineered by Monsanto to be tolerant of glyphosate, which is the active ingredient in its herbicide Roundup. The particular lines of genetically engineered alfalfa that are at issue here were designated as events J101 and J163 ("Roundup Ready alfalfa"). Monsanto owns the intellectual property rights to Roundup Ready alfalfa and licenses the technology to Forage Genetics, who is the exclusive developer of Roundup Ready alfalfa seed.

APHIS, a division of the United States Department of Agriculture, has the authority to regulate "the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," or "regulated articles." *See* 7 C.F.R. § 340.0(a)(2) & n. 1. APHIS initially classified Roundup Ready alfalfa as a regulated article. Monsanto submitted a petition in April 2004 requesting nonregulated status for events J101 and J163.

APHIS had three options: it could take no action, in which case Roundup Ready alfalfa would continue to be a regulated article; it could unconditionally deregulate Roundup Ready alfalfa, which would require the agency to make a finding of no significant impact; or it could partially deregulate Roundup Ready alfalfa, either by approving some but not all of the lines involved, or by approving the petition but imposing geographic restrictions.

APHIS published a notice in the Federal Register in November 2004 advising the public of Monsanto's petition and soliciting comments. It explained that APHIS had prepared an Environmental Assessment ("EA") in accordance with NEPA and its implementing regulations. In the EA, APHIS explained that alfalfa is pollinated by insects, primarily bees, and that insect pollination has been documented as occurring up to 2 miles from the pollen source. With regard to the threat of possible genetic contamination of non-genetically engineered alfalfa, it explained that the National Organic Program mandates buffer zones around organic production operations, the size of which are decided by the organic producer and the certifying agent on a case-by-case basis. The EA concluded that it was therefore unlikely that Roundup Ready alfalfa would have a significant impact on organic farming.

APHIS received 663 comments, 520 of which opposed the petition and 137 of which supported it. Most of the commenting alfalfa growers and seed producers supported it because they said there was a demand for weed-free alfalfa, and Roundup Ready alfalfa would provide farmers a new option for weed control by allowing farmers to apply herbicide after weeds have germinated. Most of the academic

professionals, agricultural support industries, and growers associations who commented supported the petition as well. Opponents of the petition, who included organic and conventional alfalfa growers, cited concerns that inadvertent gene transmission would occur, and that foreign and domestic markets may not accept products that cannot be guaranteed to be non-genetically engineered. They urged a full environmental evaluation through an EIS that would analyze the environmental effects of all the alternatives. *See Natural Res. Def. Council, Inc. v. Winter*, 518 F.3d 658, 688 (9th Cir.2008) ("NEPA's procedural requirements mandate that an agency take a 'hard look' at the environmental consequences of its actions."), *overruled on other grounds by Winter v. Natural Res. Def. Council, Inc.*, ---U.S. ----, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008).

On the basis of the EA and after considering the comments received, APHIS in June 2005 made a finding of no significant impact. *See* 70 Fed.Reg. 36,917, 36,918 (June 27, 2005). It therefore concluded that it did not need to prepare an EIS, and it unconditionally deregulated Roundup Ready alfalfa.

Plaintiffs filed this action in February 2006, alleging violations of NEPA and other federal statutes. The district court first considered whether APHIS had violated NEPA. After a hearing on plaintiffs' and defendants' motions for summary judgment, the district court granted plaintiffs' motion in February 2007, holding that APHIS had violated NEPA by deregulating Roundup Ready alfalfa without first preparing an EIS. The court ruled APHIS had failed to take the required "hard look" at whether and to what extent the unconditional deregulation of Roundup

Ready alfalfa would lead to genetic contamination of non-genetically engineered alfalfa. The district court then turned to the issue of an appropriate remedy for the violation.

Monsanto and Forage Genetics intervened in the action at the remedies phase. They argued that growers had already purchased Roundup Ready alfalfa seed in preparation for the spring planting season, which was underway and would be ending soon, and that it would be difficult for those growers to purchase other seed in time to plant it. After hearing argument, the court entered a preliminary injunction on March 12, 2007. The preliminary injunction enjoined all planting of Roundup Ready alfalfa and all sales of Roundup Ready alfalfa seed after March 30, 2007, pending the issuance of a permanent injunction. This allowed farmers who were prepared to plant Roundup Ready alfalfa immediately, and who had already purchased the seed, to do so. The injunction also allowed all Roundup Ready alfalfa that had been planted since the deregulation decision to be grown, harvested, and sold without restriction.

In April 2007, the court held a hearing on the scope of permanent injunctive relief. Plaintiffs sought to enjoin all future planting of Roundup Ready alfalfa, as well as the harvesting of any Roundup Ready alfalfa seed already planted, pending the completion of an EIS and a new decision on deregulation; they also requested the publication of the location of Roundup Ready alfalfa crops. Defendants asked that planting go forward, but not unconditionally. At the remedy stage, APHIS agreed for the first time that any future planting should be subject to certain conditions, including requiring isolation distances from other crops and

requiring certain harvesting conditions to minimize gene flow to non-genetically engineered alfalfa seeds.

The district court considered voluminous evidentiary submissions from both sides, including the detailed declarations of multiple witnesses regarding the scope of permanent injunctive relief and scientific papers on the factual issues involved. The parties' experts disagreed over virtually every factual issue relating to possible environmental harm, including the likelihood of genetic contamination and why some contamination had already occurred. Defendants' evidence included declarations and live testimony by Forage Genetics' president, Mark McCaslin, declarations of an APHIS official, Neil Hoffman, and a declaration from a scientist at Colorado State University, Bob Hammon, who had conducted a study sponsored by Forage Genetics on pollen movement from alfalfa-seed fields by bees. Plaintiffs' evidence included Hammon's study, which they argued supports their position, as well as declarations from seed growers whose crops had been contaminated with the Roundup Ready gene and scientists who opined that genetic contamination is likely to occur.

The court entered its permanent injunction in May 2007. It adopted a middle course in determining the appropriate remedy, enjoining new planting but refusing to enjoin harvesting of already-planted Roundup Ready alfalfa. It declined to hold a further hearing to resolve the issues that it said APHIS should resolve in the EIS. "After carefully reviewing defendants' voluminous evidence, including the evidence submitted in support of the intervenors' surreply, as well as plaintiffs' evidence, the Court declines to permit the expansion of the Roundup Ready

alfalfa market while APHIS conducts the analysis it should have prepared before it allowed for the non-permitted introduction of the crop in the first instance."

Accordingly, the district court enjoined all planting of Roundup Ready alfalfa after March 30, 2007, pending APHIS's completion of an EIS and its decision on the deregulation petition. The district court rejected the conditions proposed by the agency because it found that genetic contamination had occurred when similar conditions were in place pursuant to Forage Genetics' contracts with Roundup Ready alfalfa growers. The district court, however, also rejected the Plaintiffs' request to enjoin the harvesting and sale of Roundup Ready alfalfa seed that had already been planted. The court instead deferred to the agency and adopted "the relevant conditions proposed by APHIS."

Defendants, joined by intervenors Monsanto and Forage Genetics (collectively, "appellants"), appeal the injunction, arguing it is too broad, but neither the government nor the intervenors now question the existence of a NEPA violation. They dispute only the scope of the injunction, and whether the district court should have held a further hearing before enjoining future planting.

Scope of the Permanent Injunction

Appellants argue that the district court erred in ordering injunctive relief because it improperly presumed irreparable injury instead of applying the traditional four-factor test for the issuance of a permanent injunction, as required under *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006). They argue that, as a result, the district court's injunction was overbroad because

the court did not consider the likelihood of potential harm if Roundup Ready alfalfa was planted subject to the mitigation measures proposed by APHIS.

To obtain permanent injunctive relief, a plaintiff must show " '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.' " *N. Cheyenne Tribe v. Norton*, 503 F.3d 836, 843 (9th Cir.2007) (quoting *eBay*, 547 U.S. at 391, 126 S.Ct. 1837). This traditional balancing of harms applies in the environmental context. *Forest Conservation Council v. U.S. Forest Serv.*, 66 F.3d 1489, 1496(9th Cir.1995); *see also Lands Council v. McNair*, 537 F.3d 981, 1005 (9th Cir.2008) (en banc) ("Our law does not ... allow us to abandon a balance of harms analysis just because a potential environmental injury is at issue."). In determining the scope of an injunction, a district court has " 'broad latitude,' " *High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 641 (9th Cir.2004) (quoting *Natural Res. Def. Council v. Sw. Marine, Inc.*, 236 F.3d 985, 999 (9th Cir.2000)), and it " 'must balance the equities between the parties and give due regard to the public interest,' " *N. Cheyenne Tribe*, 503 F.3d at 842-43(quoting *High Sierra*, 390 F.3d at 642).

The Supreme Court has recognized that "the balance of harms will usually favor the issuance of an injunction to protect the environment" if injury is found to be sufficiently likely because "[e]nvironmental injury, by its nature, can seldom be adequately

remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545, 107 S.Ct. 1396, 94 L.Ed.2d 542 (1987). In *Amoco*, the Court held that a preliminary injunction had been improperly ordered because injury to the environment was "not at all probable." *Id.* This court has recognized that even when a district court finds that a NEPA violation occurred, "in 'unusual circumstances' an injunction may be withheld, or, more likely, limited in scope." *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 737 n. 18 (9th Cir.2001) (citing *Forest Conservation Council*, 66 F.3d at 1496).

The Supreme Court held in *eBay* that courts cannot grant or deny injunctive relief categorically in place of applying the four-factor test. 547 U.S. at 394, 126 S.Ct. 1837. The district court in that case had suggested that patent holders who license their patents do not suffer irreparable harm. *Id.* at 393, 126 S.Ct. 1837. The Court held that the district court had erred in adopting "expansive principles suggesting that injunctive relief could not issue in a broad swath of cases." *Id.* It held that the reversing court of appeals had also erred because it too had applied a categorical rule, that injunctions in patent cases should generally be granted once infringement and validity are established except in the "unusual case, under exceptional circumstances." *Id.* at 394, 126 S.Ct. 1837 (internal quotation marks omitted). The Court held "that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity . . . ." *Id.*

Here, the record demonstrates that the district court applied the traditional four-factor test, required by *eBay*, before issuing its injunction. It expressly recognized that an injunction does not "automatically issue" when a NEPA violation is found and said that it was required to "engage in the traditional balance of harms analysis." The court then discussed each of the four factors of the traditional balancing test and concluded that the equities favored an injunction against the future planting of Roundup Ready alfalfa.

With respect to harm, the court found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place that were similar to their proposed mitigation measures. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. The court also reasoned that appellants would be unable to enforce compliance with any proposed mitigation measures, given the government's admitted lack of resources. The court therefore did not presume that irreparable harm was likely to occur only on the basis of the NEPA violation; it concluded that plaintiffs had established that genetic contamination was sufficiently likely to occur so as to warrant broad injunctive relief, though narrower than the blanket injunction sought by plaintiffs. *See Winter v. Natural Res. Def. Council, Inc.*, --- U.S. ----, 129 S.Ct. 365, 375, 172 L.Ed.2d 249 (2008).

Appellants contend the district court did not take into account the evidence demonstrating that the likelihood of hay-to-hay transmission is extremely low

because hay is harvested before the crops bloom to 10%. The district court examined the evidence and found that weather conditions could prevent farmers from harvesting hay before 10% bloom, citing the testimony of Forage Genetics' president. The district court's finding was not clearly erroneous.

After considering the likelihood of irreparable injury, the court next considered the balance of hardships. The harm to appellants was economic, and the court reasoned that Roundup Ready alfalfa accounted for only 15% of Forage Genetics' total revenue and "much, much less of Monsanto's." It also found that any unsold seed appears to be storable for planting in later years. The court's injunction allowed Roundup Ready alfalfa that had already been planted and that was to be planted before March 30 to remain, subject to certain conditions, and only enjoined future planting, which demonstrates that the court crafted a remedy that accounted for the hardships to both sides. Monsanto and Forage Genetics contend that the district court disregarded their financial losses, but the district court considered those economic losses and simply concluded that the harm to growers and consumers who wanted non-genetically engineered alfalfa outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The district court finally considered the public interest, the fourth factor in the framework for injunctive relief. *See N. Cheyenne Tribe*, 503 F.3d at 843. The court, while recognizing that agricultural biotechnology has social value, held that it would be in the public interest to enjoin the expanded use of Roundup Ready alfalfa before its impact was studied,

because failing to do so could potentially eliminate the availability of non-genetically engineered alfalfa.

Appellants rely on *Northern Cheyenne* for the proposition that a narrower injunction should be entered here. In that case, we affirmed a district court's injunction. *Id.* at 846. *Northern Cheyenne* does not support a reversal in this case. There, the Bureau of Land Management ("BLM") had violated NEPA because its EIS failed to study an alternative method of development that the plaintiffs wanted the BLM to consider. *See id.* at 841, 844. The injunction permitted one method to proceed and prohibited other activity pending full compliance with NEPA. *Id.* We held that the district court's injunction was not an abuse of discretion. That conclusion does not support a holding that the injunction in this case was an abuse of discretion. APHIS did not take the requisite "hard look" at the impact of any form of deregulation on the environment. *See Nat. Res. Defense Council*, 518 F.3d at 688.

Appellants also argue that the district court should have deferred to APHIS's proposed interim measures because of the expertise of the government agency, despite the agency's now undisputed failure to comply with NEPA. They rely primarily on *Idaho Watersheds Project*, 307 F.3d 815. However, that case does not require a district court to adopt an agency's proposed measures as a matter of law. *In Idaho Watersheds*, to determine the terms of an injunction to protect land and streams from the effects of too much cattle grazing pending the BLM's compliance with NEPA, the district court adopted the interim measures proposed by the BLM to respond to environmental injury, which the court thought represented a "balanced approach."

Id. at 823, 830-31. Affirming, we said that "the Ninth Circuit has shown considerable deference for factual and technical determinations implicating substantial agency expertise." *Id.* at 831. Here, the agency's proposed interim measures would perpetuate a system that was found by the district court to have caused environmental harm in the past. While the agency's response may deserve deference, *Idaho Watersheds* does not require the district court to adopt it automatically. The district court did not abuse its discretion in choosing to reject APHIS's proposed mitigation measures in favor of a broader injunction to prevent more irreparable harm from occurring.

The district court applied the traditional balancing test, and not a categorical rule, in fashioning the injunction here, *see eBay*, 547 U.S. at 394, 126 S.Ct. 1837, and its factual conclusions were not clearly erroneous. The district court therefore did not abuse its discretion in formulating the remedy.

Lack of an Evidentiary Hearing

Monsanto and Forage Genetics also argue that the district court erred in declining to hold an evidentiary hearing before entering the permanent injunction. The district court had already held a hearing on whether an EIS was required, and heard testimony during a March hearing from Forage Genetics' president on the scope of preliminary injunctive relief.

Monsanto and Forage Genetics requested that the district court hold an evidentiary hearing before issuing the permanent injunction so that the district court could, as described by that court, "assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs'

witnesses." This evidence concerned the degree of the risk of environmental damage. There were voluminous documentary submissions from both sides disputing, among other things, the likelihood of genetic contamination of non-Roundup Ready alfalfa fields. APHIS did not request an evidentiary hearing.

The district court reviewed the documentary submissions, but it declined to hold a further hearing. It explained that holding the type of evidentiary hearing suggested by the intervenors "would require this Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS; defendants are in effect asking this Court to accept its truncated EIS without the benefit of the development of all the relevant data and, importantly, without the opportunity for and consideration of public comment." The court cited *Idaho Watersheds* in concluding that it did not need to conduct an extensive inquiry, involving scientific determinations, to determine what interim measures are necessary to protect the environment "while the [government] conducts studies in order to make the very same scientific determinations." 307 F.3d at 831.

Monsanto and Forage Genetics are correct that generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed. *See United States v. Microsoft Corp.*, 253 F.3d 34, 101-03(D.C.Cir.2001); *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir.1988). The district court did not believe defendants had established any material issues of fact that were in dispute in the case before the court. Rather, it viewed

the disputed matters to be issues more properly addressed by the agency in the preparation of an EIS.

The injunction at issue here, as in *Idaho Watersheds*, is not a typical permanent injunction, which is of indefinite duration. A permanent injunction to ensure compliance with NEPA has a more limited purpose and duration. Thus, in *Idaho Watersheds*, a case involving a NEPA violation, this court held that an evidentiary hearing was not required before issuing an injunction. *See* 307 F.3d at 831. We distinguished this context from *Microsoft*, and the "normal injunctive setting," principally because *Idaho Watersheds* involved interim measures that would be in place only until the EIS was completed, at which point the parties would have "extensive input" into the determination of which measures would be adopted permanently. *Id.* at 831; *accord Mont. Wilderness Ass'n v. Fry*, 310 F.Supp.2d 1127, 1155-56 (D.Mont.2004) (holding that, under *Idaho Watersheds*, an evidentiary hearing was not required before imposing interim injunctive relief). The district court there had sought to avoid the catch-22 situation where an evidentiary hearing would require it to perform the same type of extensive inquiry into environmental effects that the ordered EIS will require the government agency to perform. *Idaho Watersheds*, 307 F.3d at 831. We agreed with the district court's approach, holding that an evidentiary hearing was not required because the measures were "interim measures designed to allow for a process to take place which will determine permanent measures, and all parties will have adequate opportunity to participate in the determination of permanent measures (and if need be challenge the outcome in court)." *Id.* We observed that requiring a

hearing would duplicate the BLM's efforts and divert its resources from those efforts. *Id.* The district court here correctly denied a hearing because the same situation is presented in this case.

Monsanto and Forage Genetics also contend that even if *Idaho Watersheds* authorizes entry of a permanent injunction without an evidentiary hearing, it does so only if the court adopts the agency's recommendation. We explained in *Idaho Watersheds*, however, that the key reason a further evidentiary hearing was not required was that the injunction would be in place only until the necessary environmental studies were conducted. *Id.* In this case, as in *Idaho Watersheds*, the government does not contend that a further hearing is required, perhaps in order to avoid the duplication of resources we described in *Idaho Watersheds*. The dissent insists on remanding for a hearing that the government has never contended would be appropriate in this case.

The district court here considered extensive evidentiary submissions from all parties pertaining specifically to the remedy phase, as it was required to do. *See Microsoft*, 253 F.3d at 103 (holding that district court had erred in failing to consider the remedies-phase evidentiary submissions of defendant). It held two hearings during the remedies phase, one of which included testimony from the president of Forage Genetics on the scope of preliminary injunctive relief. It then determined that it should not conduct a hearing that would duplicate APHIS's efforts in preparing the EIS ordered by the court.

The dissent is thus incorrect in stating that the district court failed to hold an evidentiary hearing because the district court held one hearing on the

nature of the NEPA violation, two hearings on the scope of injunctive relief, which included testimony from Forage Genetics' president, and reviewed extensive documentary submissions relating to an appropriate remedy. What the district court did not do was to hold an additional evidentiary hearing to resolve the very disputes over the risk of environmental harm that APHIS would have to consider in the EIS. Nor is the dissent correct that the district court should have given conclusive deference to the limited mitigation measures APHIS proposed during the remedy phase. The district court adopted all of APHIS's proposed conditions that pertained to alfalfa that was already planted. But because the court had already determined that future planting should be enjoined pending the EIS, the court declined to impose APHIS's conditions that would have permitted future planting. Under these circumstances, there was no abuse of discretion.

The injunction involved only interim measures pending APHIS's compliance with NEPA, and the district court considered extensive remedies-phase evidence. The court did not err in declining to hold a further hearing before entering the injunction pending the agency's completion of environmental study the law undisputedly required it to perform before approving this product for unrestricted use.

The district court's order is **AFFIRMED**.

N. RANDY SMITH, Circuit Judge, dissenting:

The district court's failure to conduct the requisite evidentiary hearing prevents me from joining the majority's opinion. The majority correctly recognizes that the district court was required to conduct an evidentiary hearing before issuing a permanent

injunction under Federal Rule of Civil Procedure 65 unless (1) the facts were undisputed; or (2) the adverse party expressly waived its right to an evidentiary hearing. *Charlton v. Estate of Charlton*, 841 F.2d 988, 989(9th Cir.1988). Despite recognizing this clear precedent, the majority affirms the district court's decision to proceed without the requisite evidentiary hearing, and, in so doing, creates an altogether new exception to the evidentiary hearing requirement we recognized in *Charlton*.

The majority acknowledges that the facts were sharply disputed by the parties. To be sure, the parties disputed almost every element of the facts underlying the proposed injunction. Specifically, the parties disputed the risk of genetic contamination that could occur if the district court did not enjoin the further planting of Roundup Ready alfalfa while APHIS prepared the EIS. Given that the parties disputed the facts underlying the need for, and scope of, any injunctive relief, the first recognized exception to the evidentiary hearing requirement was unavailable. *See Charlton*, 841 F.2d at 989.

The second recognized exception was unavailable too. As the district court noted, Monsanto and Forage Genetics requested an evidentiary hearing "apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." In discussing Monsanto's and Forage Genetics' request for an evidentiary hearing, the majority notes APHIS's failure to request an evidentiary hearing. This failure, however, is insignificant given that Monsanto and Forage Genetics already had made their request.

Because the parties did not consent to proceed without an evidentiary hearing, the other recognized exception to the evidentiary hearing requirement was unavailable. *See id.* Given those facts, we should reverse to allow the district court to conduct an evidentiary hearing. But that is not what the majority does here.

The majority instead relies on *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 823 (9th Cir.2002), to create an altogether new exception to the evidentiary hearing requirement. The majority reasons that, because the injunction will only last as long as it takes APHIS to conduct an EIS, this is not a typical permanent injunction requiring typical procedural safeguards. The majority next assumes that an evidentiary hearing would result in waste of agency resources, because the hearing would require consideration of the same issues that APHIS must resolve in conjunction with the EIS.

As the majority correctly recognizes, we affirmed the district court's refusal to conduct an evidentiary hearing in *Idaho Watersheds* in light of the temporary nature of the injunction. But this case isn't *Idaho Watersheds*. There, the district court deferred to the agency's recommendations and expertise in granting a temporary injunction—thereby resulting in an efficient resolution pending completion of the agency determinations. Conversely, in this case, the district court expressly rejected APHIS's proposed injunction and independently fashioned a permanent injunction without the benefit of live testimony subject to the adversarial process. In its revised opinion, the majority notes that the court "deferred to the agency and adopted 'the relevant conditions proposed by the

APHIS.' " What the district court did was defer to APHIS only with regard to its recommendations concerning the already planted RRA. No deference, however, was given to APHIS's proposal that "prior to APHIS' [s] completion of the EIS . . . RRA can be grown, harvested and used, provided it is in accordance with six stringent, science-based requirements designed to mitigate the potential environmental harms specified by this Court." By picking and choosing when to afford deference, the court's deference is tantamount to no deference at all. These shortcomings resulted in a critical failure by the district court and deprived the parties of important procedural rights when it came to shaping the scope of any potential injunction.

In its amended opinion, the majority states that the district court "held one hearing on the nature of the NEPA violation [and] two hearings on the scope of injunctive relief. . . ." While the majority would like to describe the hearings in that manner, the record does not confirm such a description. The record instead indicates that the district court held six hearings on motions by the parties. In five of these hearings, only argument by lawyers was heard. In one hearing Forage Genetics president Mark McCaslin was allowed to speak without notice to the parties or opportunity for cross-examination.

The majority argues that the district court didn't need to conduct an evidentiary hearing, because it held the aforementioned hearings, had documentary submissions, and had the benefit of this testimony from Mr. McCaslin. With due respect to both counsel and Mr. McCaslin, this falls far short of the standards we have articulated for a hearing prior to issuing an

injunction. The hearings cited by the majority were simply arguments by counsel construing the written submissions and documentary evidence. Although helpful, argument by counsel and documentary submissions are no substitute for live testimony when it comes to determining the nature and extent of the alleged injury, where the balance of hardship lies, and the scope of the injunction. Based on this record, Mr. McCaslin's statement was little better than no testimony.

The district court could have used the evidentiary hearing to better ascertain the nature of the alleged injury and to further understand the balance of the hardships associated with the parties' varying proposals for injunctive relief. It didn't. The district court also could have used the hearing to test the merits of the parties' positions. An evidentiary hearing would have allowed for cross examination of the witnesses on their written testimony and submissions. Instead the district court rejected the agency's proposal and fashioned its own permanent injunction based on argument of counsel, the written record, and ad hoc testimony from Mr. McCaslin. These shortcomings are significant, because the district court might have reached a different result had it held an evidentiary hearing before reaching a decision.

In such a hearing, the district court did not need to resolve the very disputes over the risk of environmental harm that APHIS might resolve differently in an EIS—as the majority contends in its amended opinion. It only needed to decide, listening and observing the witnesses, what it would do in the mean time. The district court failed to do so.

The evidentiary hearing requirement is essential because it allows the district court an opportunity to consider the witnesses' credibility in the face of cross examination. That step is what justifies the abuse of discretion standard of review under which we consider a district court's decision to grant or deny injunctive relief. If a district court skips the requisite evidentiary hearing, we have exactly the same record on appeal as the district court did below. In that circumstance, I see no reason to afford the district court any discretion when reviewing its decision to grant or deny an injunction. For that reason, I consider it to be an abuse of discretion for a district court not to hold an evidentiary hearing unless the case fits in either of the recognized *Charlton* exceptions or the district court accepts the agency's proposal for temporary injunctive relief, as occurred in *Idaho Watersheds*.

Based on this record, I have serious concerns about the scope of the injunction entered by the district court. At best, the record reflects sparse evidence of hay-to-hay gene transmission of RRA alfalfa in some areas of the country under certain planting conditions. Further, I see no good evidence of hay-to-seed or seed-to-seed gene transmission. Yet the district court entered a nationwide injunction on the planting of Roundup Ready alfalfa while APHIS completes an EIS. This nationwide injunction has severe economic consequences for Monsanto, Forage Genetics, and for the farmers and distributors who planned on RRA alfalfa being available. I would be more comfortable with a nationwide injunction had the district court held an evidentiary hearing to consider live testimony, listened to cross examination, and resolved any credibility issues between the witnesses. But no such

hearing occurred, and I therefore have no confidence in the need for a nationwide injunction pending completion of the EIS.

By affirming the district court's refusal to conduct an evidentiary hearing, the majority has created a third exception to the evidentiary hearing requirement. Under this decision, a district court now can forego conducting an evidentiary hearing simply because (1) the injunction may dissolve at some point and (2) the issues, to be raised at the hearing, overlap with the issues the agency must consider in making a final decision regarding the controversy. Instead of giving deference to the agency's expertise, *see The Lands Council v. McNair*, 537 F.3d 981, 987-88, 991-93 (9th Cir.2008) (en banc), the majority gives deference to the district court, despite its wholesale rejection of the agency's proposal for an injunction and its failure to hold an evidentiary hearing. There aren't many environmental cases that don't fit into the majority's newly-created exception. This is a mistake, as it would eliminate a "significant procedural step[,]" *Charlton*, 841 F.2d at 989, without any real justification. I would instead remand so that the district court could conduct an evidentiary hearing on the merits and scope of the permanent injunction.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON SEED FARMS, et al.,
Plaintiffs,
v.
MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al.,
Defendants. /

No. C 06-01075 CRB

MEMORANDUM AND ORDER

In this lawsuit plaintiff alfalfa growers along with the Sierra Club and other farmer and consumer associations challenge the Department of Agriculture's decision to deregulate alfalfa genetically engineered to resist the herbicide glyphosate, the active ingredient in RoundUp ("Roundup Ready alfalfa"). Plaintiffs bring their claims pursuant to the National Environmental Policy Act ("NEPA"), the Endangered Species Act ("ESA"), and the Plant Protection Act ("PPA"). Now pending before the Court are the parties' cross-motions for summary judgment. The motions raise a close question of first impression: whether the introduction of a genetically engineered crop that might significantly decrease the availability or even eliminate all non-genetically engineered varieties is a "significant environmental impact" requiring the preparation of an environmental impact statement, at least when it involves the fourth largest crop in the United States.

BACKGROUND

The federal Plant Protection Act gives the Secretary of the United States Department of Agriculture ("USDA") the authority to adopt regulations preventing the introduction and dissemination of plant pests. 7 U.S.C. § 7711(a); Center for Food Safety v. Johanns, 451 F.Supp.2d 1165, 1176 (D. Haw. 2006). Pursuant to this authority, the USDA, through the Animal and Plant Health Inspection Service ("APHIS"), regulates "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests." 7 C.F.R. § 340.0(a)(2) n.1. Such products/organisms are known as "regulated articles." APHIS originally considered Roundup Ready alfalfa a regulated article; as such, it was unlawful for any person to introduce the alfalfa without first obtaining permission from APHIS. Id.

Any person may submit a petition seeking a determination that a regulated article does not present a plant pest risk and therefore should not be regulated. 7 C.F.R. § 340.6. In May 2003, Monsanto, the manufacturer of Roundup, submitted a petition requesting nonregulated status for Roundup Ready alfalfa, designated as event J101 and J163. Administrative Record ("AR") 5482. Roundup Ready alfalfa is engineered to be glyphosate-tolerant by inserting a gene that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase into the alfalfa genome. AR 5501.

APHIS had several possible responses: it could approve the petition in whole, approve the petition in part, or deny the petition. AR 5503. If it denied the petition, commercial-scale production of Roundup

Ready alfalfa would continue to be precluded, although the plant could still be grown in field trials, as it has since 1998. AR 5503. APHIS could also determine that Roundup Ready alfalfa poses no significant risk in certain geographic areas, but a significant risk in others, and therefore approve the petition in part; that is, approve the petition with a geographic limitation on where the genetically engineered alfalfa could be grown. AR 5504. Finally, APHIS could approve the petition in whole, which means that Roundup Ready alfalfa would no longer be subject to USDA regulation. AR 5505.

Before deciding Monsanto's petition, APHIS prepared an Environmental Assessment ("EA") and took public comments on the EA and the petition for deregulation. Of the 663 comments received by the agency, 520 opposed deregulation. AR 5487.

One of the primary objections raised is that gene transmission may occur between glyphosate tolerant alfalfa and conventional and organic alfalfa, that is, that conventional and organic alfalfa will become "contaminated" with the engineered gene that makes Roundup Ready alfalfa tolerant to glyphosate. Such gene transmission is possible because alfalfa is pollinated by bees "and so the potential exists to move pollen from the glyphosate tolerant crop to hay and seed fields, as well as wild populations of alfalfa." AR 5488. Indeed, it is undisputed that insect pollination for alfalfa can occur up to at least two miles from the pollen source. Id. Farmers complained to APHIS that if Roundup Ready alfalfa is deregulated they will no longer be able to market their products as "organic," or at least as non-genetically engineered, and that this "contamination" will also impact those

who sell organic livestock or livestock that is not fed any genetically engineered foods. AR 5488, 5491, 5495. In addition, 75 percent of the alfalfa exported from the United States (five percent of the alfalfa market) is exported to Japan and Japan does not permit the import of glyphosate tolerant alfalfa; thus, the introduction of Roundup Ready alfalfa might also impact the export market. AR 5487.

Commentators also expressed concern that the deregulation of Roundup Ready alfalfa, and the concomittant increase in the use of Roundup, will cause the development of additional glyphosate-resistant weeds, as well as a dramatic increase in the amount of Roundup used in the environment.

Nonetheless, in June 2005, APHIS issued a Finding of No Significant Impact ("FONSI") and approved Monsanto's deregulation petition in whole; that is, the agency concluded that Roundup Ready alfalfa should be deregulated and sold without direct regulation by the USDA. AR 5485-5526.

The FONSI acknowledges that once Roundup Ready alfalfa is deregulated, it will not be subject to any "isolation distances;" that is, it will not be required to be grown more than two miles from conventional or organic alfalfa crops. AR 5488; see also AR 5495 ("If APHIS grants non-regulated status to a transgenic events, APHIS does not have any further regulatory authority over this particular transgenic event"). APHIS nevertheless concluded that the risk of gene transmission is not significant because "organic production operations must develop and maintain an organic production system plan that outlines the steps it will take to avoid cross pollination from neighboring operations." AR 5488. In other words, it would be "up

to the individual organic seed or hay grower to institute those procedures that will assure" that their crops will not include any genetically engineered alfalfa. AR 5491. APHIS also noted that the states would still have the authority to establish some type of production zone. AR 5495. As for exports to Japan, APHIS concluded, without elaboration, that "[b]y employing reasonable quality control, it is highly unlikely that the level of glyphosate tolerant alfalfa will exceed 1% in conventional alfalfa hay" and that since Japan allows one percent of exports of a crop to contain genetically modified product, exports to Japan would not be affected. AR 5488.

In the EA, APHIS concluded that organic farmers and farmers who otherwise do not want to grow genetically engineered alfalfa will not be significantly impacted by the commercial use of Roundup Ready alfalfa because (1) non-genetically engineered alfalfa will "likely still be sold and available to those who wish to plant it;" and (2) farmers purchasing seed will know what they are purchasing because the seed will be labeled as glyphosate tolerant. AR 5511.

APHIS agreed with the objectors that the deregulation of Roundup Ready alfalfa could lead to the development of additional glyphosate-resistant weeds, but reasoned that this impact was not significant because weed species have developed resistance to every widely used herbicide; alternative herbicides are available to minimize the problem; and, in any event, "good stewardship may be the only defense against this potential problem." AR 5492.

Plaintiffs now challenge APHIS's decision to deregulate Roundup Ready alfalfa.

DISCUSSION

I. NEPA

NEPA "requires a federal agency such as [APHIS] to prepare a detailed EIS for all 'major Federal actions significantly affecting the quality of the human environment.'" Blue Mountains Biodiversity Project v. Blackwood, 161 F.3d 1208, 1211-12 (9th Cir. 1998) (quoting 42 U.S.C. § 4332(2)(C)). "NEPA ensures that the agency . . . will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience." Id. (internal quotation marks and citation omitted).

Accordingly, "[a] threshold question in a NEPA case is whether a proposed project will 'significantly affect' the environment, thereby triggering the requirement for an EIS." Id. "Where an EIS is not categorically required, the agency must prepare an Environmental Assessment to determine whether the environmental impact is significant enough to warrant an EIS." Ocean Advocates v. U.S. Army Corps of Engineers, 402 F.3d 846, 863 (9th Cir. 2005). "An EA is a concise public document that briefly provide[s] sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact." Blue Mountains Biodiversity Project, 161 F.3d at 1212.

Here, APHIS prepared an EA and, after receiving public comment, issued a finding of no significant impact and approved the deregulation of Roundup Ready alfalfa. See Anderson v. Evans, 371 F.3d 475, 488 (9th Cir. 2004) (if an EA results in a "finding of no significant impact"--known as a FONSI--the agency

need not prepare an environmental impact statement). Plaintiffs contend that APHIS is required to prepare an EIS.

A. Standard of Review

The Court must determine whether APHIS's "decision was based on consideration of the relevant factors, or whether its actions were arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law." Blue Mountains Biodiversity Project, 161 F.3d at 1211 (internal quotation marks and citation omitted). "In short, [the Court] must ensure that the agency has taken a 'hard look' at the environmental consequences of its proposed action." Id. "A hard look includes considering all foreseeable direct and indirect impacts.'" Earth Island Inst. v. U.S. Forest Serv., 442 F.3d 1147, 1159 (9th Cir. 2006) (internal quotation marks and citation omitted). "An agency's decision not to prepare an EIS will be considered unreasonable if the agency fails to supply a convincing statement of reasons why potential effects are insignificant." Blue Mountains Biodiversity Project, 161 F.3d at 1211 (internal quotation marks and citation omitted); see also Ocean Advocates, 402 F.3d at 865 ("[T]he agency must put forth a 'convincing statement' of reasons that explain why the [agency action] will impact the environment no more than insignificantly"). "The statement of reasons is crucial to determining whether the agency took a 'hard look' at the potential environmental impact of a project." Blue Mountains Biodiversity Project, 161 F.3d at 1212 (internal quotation marks and citation omitted).

B. Analysis

"[A]n EIS *must* be prepared if 'substantial questions are raised as to whether a project *may* cause

significant degradation of some human environmental factor.'" Idaho Sporting Cong. v. Thomas, 137 F.3d 1146, 1149 (9th Cir. 1998) (quoting Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992)). "Thus to prevail on a claim that [APHIS] violated its statutory duty to prepare an EIS, a plaintiff need not show that significant effects will in fact occur. It is enough for the plaintiff to raise substantial questions whether a project may have a significant effect on the environment." Blue Mountains Biodiversity Project, 161 F.3d at 1212 (internal quotation marks and citation omitted). "Put another way, a proposal can be considered controversial if substantial questions are raised as to whether a project may cause significant degradation of some human environmental factor." Anderson, 371 F.3d at 489.

"In determining whether a federal action requires an EIS because it significantly affects the quality of the human environment, an agency must consider what 'significantly' means." Ocean Advocates, 402 F.3d at 865. "Significantly," has two components: context and intensity. Id. (citing 40 C.F.R. § 1508.27). "Context refers to the setting in which the proposed action take place." Id. (citing 40 C.F.R. § 1508.27(a)). "Intensity means 'the severity of the impact.'" Id. (citing 40 C.F.R. § 1508.27(b)).

Several factors must be considered in evaluating intensity, including the "degree to which the effects on the quality of the human environment are likely to be highly controversial;" "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks;" and "[t]he degree to which the proposed action affects

public health and safety." 40 C.F.R. § 1508.27(b)(2), (4), (6).

The context of the inquiry in this case is undisputed. Alfalfa is the fourth most widely grown crop in the United States. The bulk of alfalfa seed (as opposed to alfalfa forage) is grown in limited geographic areas within a few states. California is the largest producer of alfalfa seed, and California, Idaho, Washington and Nevada together produce 85 percent of all domestic alfalfa seed. In this context, plaintiffs identify what they believe are several significant environmental impacts that will be caused by Roundup Ready alfalfa, or that at least may be caused by the deregulation of the genetically engineered alfalfa.

1. Gene transmission to non-genetically engineered alfalfa

Plaintiffs contend that one significant environmental impact resulting from the introduction of Roundup Ready alfalfa is that genetically engineered alfalfa will modify non-genetically engineered alfalfa such that it, too, will contain the gene that confers tolerance to the herbicide glyphosate. Plaintiffs label such effect "biological contamination." Biological contamination can occur through pollination of non-genetically engineered plants by genetically engineered plants or by the mixing of genetically engineered seed with natural, or non-genetically engineered seed.

Alfalfa seeds are pollinated by bees and, as a result, there is a realistic potential for contamination from seed fields to nearby seed fields; indeed, APHIS admits that insects pollinate alfalfa up to two miles from the pollen source. AR 5488. Such gene transmission is especially likely in this context given the geographic

concentration of alfalfa seed production. Once the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread. AR 4287. And alfalfa is a perennial crop; the crop is only replanted every three to four years.

Plaintiffs complain that the "contamination" of organic and conventional crops with the genetically engineered gene will have negative economic and socioeconomic effects on farmers. Organic farmers will no longer be able to market their seed as non-genetically engineered, rendering their crops less valuable; consumers pay a premium for organic and non-genetically engineered food. Similarly, organic livestock farmers will have a more difficult time purchasing non-genetically engineered alfalfa as food for livestock and thus will be unable to market their livestock as organic or at least fed with non-genetically engineered food. All of these farmers may be required to test their crops and livestock for traces of the genetically-engineered alfalfa. Even non-organic farmers who want to raise genetically-engineered free plants and livestock will be impacted.

APHIS acknowledges that once Roundup Ready alfalfa is deregulated the government will not be able to impose isolation distances on the growers of genetically engineered alfalfa; in other words, it cannot ensure that farmers using the genetically engineered seed will be more than two miles away from seed farmers who do not wish to grow engineered alfalfa. AR 5488. APHIS nonetheless concluded that the introduction of Roundup Ready alfalfa will have no significant environmental impact, reasoning as follows:

> [T]he National Organic Program, which is administered by USDA's Agricultural Marketing Service, requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances, such as modified genes, from adjoining land that is not under organic management. However, the determination of the size of the buffer zones is left up to the organic producer and the certifying agent on a case-by-case basis. Furthermore, organic production operations must develop and maintain an organic production system plan that outlines the steps it will take to avoid cross pollination from neighboring operations.

AR 5488, 5510. It also reasoned that federal organic standards do not require the testing of inputs or products for genetically engineered genes and that the unintentional presence of the engineered genes will not "necessarily" constitute a violation of national organic standards. AR 5511.

In the EA, APHIS concluded, without further elaboration, that non-genetically engineered alfalfa seed "will likely still be sold and will be available to those who wish to plant it," and that genetically engineered seed will be marketed and labeled as glyphosate tolerant so farmers will know when they are purchasing Roundup Ready alfalfa seed. AR 5511. APHIS also found that gene transmission is not likely to occur with forage as opposed to seed crops because forage fields are typically harvested before the seed is set and allowed to mature. Id.

APHIS's reasons for concluding that the potential for the transmission of the genetically engineered gene is not significant are not "convincing" and do not demonstrate the "hard look" that NEPA requires. See Blue Mountains Biodiversity Project, 161 F.3d at 1211. APHIS did not conclude that gene transmission would not occur; indeed, an internal APHIS email acknowledges that "[i]t may be hard to guarantee that seeds or sprouts are GE free." AR 2816. Instead, it in effect concluded that whatever the likelihood of gene transmission, such impact is not significant because it is the organic and conventional farmers' responsibility to ensure that such contamination does not occur. It rested its "no significant impact" decision on this conclusion even though it made no inquiry into whether those farmers who do not want to grow genetically engineered alfalfa can, in fact, protect their crops from contamination, especially given the high geographic concentration of seed farms and the fact that alfalfa is pollinated by bees that can travel more than two miles. Neither the EA nor the FONSI identify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby genetically engineered seed farm, even assuming the farmer maintains a "buffer zone."

"Preparation of an EIS is mandatory where uncertainty may be resolved by further collection of data, or where the collection of data may prevent speculation on potential . . . effects. The purpose of an EIS is to obviate the need for speculation by insuring that available data are gathered and implemented prior to the proposed action." National Parks Conservation Ass'n v. Babbitt, 241 F.3d 722, 732 (9th Cir. 2001) (internal quotation marks and citation omitted). The

further collection of data can inform APHIS as to the likely extent of any gene transmission and the realistic measures, if any, that may be taken to prevent or at least reduce such contamination. Such data is especially important given that one option APHIS has is to approve Monsanto's "petition with a geographic limitation stipulating that the Roundup Ready could only be grown without APHIS authorization in certain geographic areas." AR 5504. APHIS's rejection of this option without making any inquiry into the extent of likely gene transmission from genetically engineered seed crops to non-engineered seed crops is arbitrary and capricious; it did not obtain the very information it needs to determine if such an option is warranted. See Earth Island Institute, 442 F.3d at 1160 ("If an agency has failed to make a reasoned decision based on an evaluation of the evidence, [a court] may properly conclude that the agency has acted arbitrarily and capriciously."); Foundation for N. Am. Wild Sheep v. U.S. Dep't of Agr., 681 F.2d 1172, 1178 (9th Cir. 1982) (holding that agency violated NEPA when its EA "failed to address certain crucial factors, consideration of which was essential to a truly informed decision whether or not to prepare an EIS").

APHIS's conclusion that forage alfalfa will not be contaminated is also arbitrary and capricious. APHIS baldly concluded that such gene transmission is not likely because farmers typically harvest alfalfa forage fields before the seed matures. APHIS failed to consider, however, that because of weather--which is beyond a farmer's control--a farmer cannot always harvest his field at the most optimal time. APHIS made no inquiry into how often farmers are actually able to harvest their forage crop before seeds mature

and no inquiry into the likelihood of gene transmission when they cannot. Without such data, APHIS's conclusion is arbitrary. See Earth Island Institute, 442 F.3d at 1159 ("A hard look should involve a discussion of adverse impacts that does not improperly minimize negative side effects").

APHIS's reasoning that farmers will not "necessarily" be prohibited from labeling their products as organic is wholly inadequate. First, the statement itself is equivocal; even APHIS is uncertain whether farmers can still label their products organic under the federal government's organic standards. Second, many farmers and consumers have higher standards than what the federal government currently permits; to these farmers and consumers organic means not genetically engineered, even if the farmer did not intend for his crop to be so engineered. And, as APHIS acknowledges, many countries, including Japan, do not allow for the importation of genetically engineered alfalfa regardless of what the United States government permits. Third, and most importantly, APHIS's comment simply ignores that these farmers do not want to grow or feed to their livestock genetically engineered alfalfa, regardless of how such alfalfa can be marketed.

APHIS's assertion that exports to Japan will not be harmed because Japan allows one percent of its imported alfalfa to be transgenic and "[b]y employing reasonable quality control, it is highly unlikely that the level of glyphosate tolerant alfalfa will exceed 1% in conventional alfalfa hay," AR 5488, is also not convincing. Neither the EA nor the FONSI contain any reference to any material in support of APHIS's conclusion that gene transmission is "highly unlikely"

to occur with "reasonable quality control." APHIS does not identify any "quality control" that will prevent gene transmission between neighboring seed farms. It similarly does not identify any material to support its EA statement that non-genetically engineered alfalfa will "likely still be sold and available to those who wish to plant it." AR 5511. See Blue Mountains Biodiversity Project, 1161 F.3d at 1214 ("The EA contains virtually no reference to any material in support of or in opposition to its conclusions. That is where the Forest Service's defense of its position must be found").

APHIS argues in its brief that the extent of any gene transmission is, in any event, irrelevant because NEPA requires an agency to consider physical environmental impacts, not economic or financial impacts. APHIS overstates the law. To determine whether NEPA requires an agency to consider a particular effect, courts must "look at the relationship between that effect and the change in the physical environment caused by the major federal action at issue." Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 766, 773 (1983); see also San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n, 449 F.3d 1016, 1029 (9th Cir. 2006) ("[T]he essential analysis must focus on the closeness of the relationship between the change in the environment and the 'effect' at issue") (internal quotation marks and citation omitted); Ashley Creek Phosphate Co. v. Norton, 420 F.3d 934, 943 (9th Cir. 2005) ("NEPA does not require an agency to assess all impacts of a project, only those that have a 'reasonably close causal relationship' with 'a change in the physical environment"). Economic effects are relevant "when

they are '*interelated*' with 'natural or physical environmental effects.'" Ashley Creek Phosphate Co., 420 F.3d at 944 (quoting 40 C.F.R. § 1508.14 ("[E]conomic or social effects are not intended by themselves to require preparation of an environmental impact statement. When an environmental impact statement is prepared and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment")).

Here, the economic effects on the organic and conventional farmers of the government's deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment; namely, the alteration of a plant specie's DNA through the transmission of the genetically engineered gene to organic and conventional alfalfa. APHIS was required to consider those effects in assessing whether the impact of its proposed action is "significant." And, in fact, APHIS did mention those effects in the FONSI and EA, but, as explained above, its reasons for concluding that the effect on organic and conventional farmers is not significant are not "convincing."

Finally, the government argues that even if the deregulation of Roundup Ready alfalfa could result in the elimination of all non-genetically engineered alfalfa--in other words, there would be no alfalfa grown in the United States that does not contain the engineered gene that confers tolerance to glyphosate--such a result would still not constitute a significant environmental impact because APHIS has determined that the introduction of that gene to alfalfa is harmless to humans and livestock, that is, it is not toxic or

pathogenic. Draft Transcript of January 19, 2007 Hearing at 54-55. APHIS's position is based on its finding that the engineered gene is similar to another gene already present in non-engineered alfalfa and is the equivalent to a natural enzyme found in both green plants and microorganims that are common in nature. AR 5482, 5483, 5490-91, 5501-5502, 5491. In sum, APHIS concluded that the engineered enzyme is equivalent in all biological respects to those that are common and harmless in nature and therefore the introduction of that engineered gene into conventional or organic alfalfa is not a significant environmental impact as a matter of law.

The Court accepts, as it must, the agency's determination that Roundup Ready alfalfa does not have any harmful health effects on humans or lifestock. See Natural Res. Defense Council, Inc. v. EPA, 863 F.2d 1420, 1430 (9th Cir. 1988) ("A reviewing court should be at its most deferential in reviewing an agency's scientific determinations in an area within the agency's expertise"). Public health and safety, however, is only *one* of factors that an agency should consider when determining whether a major federal action may have a significant environmental impact. 40 C.F.R. § 1508.27(b). The government does not cite any case, and the Court is aware of none, which holds that an impact is not significant simply because a federal agency determines that the major federal action does not jeopardize the public's health and safety. The paucity of caselaw is unsurprising given that one of Congress's express goals in adopting NEPA was to "attain the widest range of beneficial uses of the environment without degradation, risk to health and safety, *or other undesirable and unintended*

consequences." 42 U.S.C. § 4331(b)(3) (emphasis added). A federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, is an undesirable consequence: another NEPA goal is to "maintain, wherever possible, an environment which supports diversity and variety of individual choice." 42 U.S.C. § 4331(b)(4).

To put it another way, if the government's action could eliminate all alfalfa, there would be no dispute that such action has a significant environmental impact, even though the primary impact is the economic effect on alfalfa and livestock farmers. For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop. The government's apparent belief that the farmers' and consumers' choice is irrational because the engineered gene is similar in all biological respects to a gene found in nature (although never in alfalfa) is beside the point. An action which potentially eliminates or least greatly reduces the availability of a particular plant--here, non-engineered alfalfa--has a significant effect on the human environment. See 40 C.F.R. § 1508.27(b) ("A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial").

One other point bears mention. At oral argument the Court asked the government why APHIS addressed (albeit inadequately) the economic impact on farmers if it is the agency's position that, regardless of how much gene transmission occurs, such transmission is insignificant because it is harmless. The government candidly explained that it addressed these possible

effects because Roundup Ready alfalfa is the first crop that has been engineered to resist a herbicide "and in which the record suggests that there's at least a chance that the [genetically engineered] gene could be transmitted." Draft Transcript of January 19, 2007 Hearing at 53. The government's response highlights that APHIS is operating in uncharted territory. In light of the Court's conclusion that the permanent modification of a plant's genetic makeup through genetic engineering is an effect on the human environment, and the evidence that such transmission can and will occur, and that APHIS did not adequately analyze the extent of such transmission, the possible effects of APHIS's deregulation decision are "highly uncertain or involve unique or unknown risks." 40 C.F.R. § 1508.27(5).

The Court cautions that it is not ruling that Roundup Ready alfalfa is harmful to consumers or livestock. Rather, the significant impact that requires the preparation of an EIS is the possibility that the deregulation of Roundup Ready alfalfa will degrade the human environment by eliminating a farmer's choice to grow non-genetically engineered alfalfa and a consumer's choice to consume such food.

2. The development of alfalfa weeds resistant to herbicides

Plaintiffs also complain that the deregulation of Roundup Ready alfalfa will cause Roundup-resistant weeds, and that such an effect is sufficiently significant to require the preparation of an EIS. APHIS acknowledges that the use of Roundup Ready alfalfa may result in the development of Roundup-tolerant weeds. AR 5492. The resistance develops because of the increased use of Roundup on the crops. APHIS

found that such a possible impact nevertheless does not warrant the preparation of an EIS because weed species often develop resistance to herbicides and the agricultural community is addressing the issue. "Alternative herbicides and strategies are available that may minimize the problem. Based on the comments, the alfalfa growers and weed scientists understand that good stewardship may be the only defense against this potential problem." AR 5492

APHIS's reasons for finding the development of glyphosate resistant weeds not to be significant are not convincing. Reasoning that weed species often develop resistance to herbicides is tantamount to concluding that because this environmental impact has occurred in other contexts it cannot be significant. Nothing in NEPA, the relevant regulations, or the caselaw support such a cavalier response.

The assertion that "good stewardship" may be the only defense against such weeds is equally unconvincing. Such a conclusion is not the same as a finding that the development of the weeds is not a significant environmental impact. This is especially so given that neither the FONSI nor the EA contain any analysis as to what exactly constitutes good stewardship and how likely it is to be practiced successfully. See Blue Mountains Biodiversity Project, 161 F.3d at 1214. There may be ways to reduce the proliferation of weeds, but if farmers are not engaging (or cannot engage) in those practices, then the availability of those practices does not ameliorate the potential environmental impact.

Finally, APHIS failed to evaluate the cumulative impact of the deregulation of Roundup Ready alfalfa. 40 C.F.R. § 1508.7 ("'Cumulative impact' is the impact

on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (Federal or non-federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.") While alfalfa is the first large scale perennial Roundup Ready crop, APHIS has deregulated other Roundup Ready crops, including corn and soybeans, and other deregulation petitions are pending. While the deregulation of one crop in and of itself might not pose a significant risk for the development of glyphosate resistant weeds, when all the crops are considered cumulatively such a risk may become apparent. There is nothing in the FONSI or EA that suggests APHIS even considered how much Roundup use will increase, or even how much such use has increased since the introduction of the other Roundup Ready crops; to the contrary, the EA specifically states that it "does not address the separate issue of the potential use of the herbicide glyphosate in conjunction with these plants." AR 5501. APHIS's failure to consider in the context of the development of Roundup resistant weeds that there are already other Roundup Ready crops on the market, and more crops seeking to enter the market, means that it did not take the "hard look" NEPA requires.

3. Increased use of glyphosate

In a related argument, plaintiffs assert that--even apart from the development of glyphosate-resistant weeds--APHIS failed to consider that the deregulation of Roundup Ready alfalfa will result in the increased use of Roundup, and likewise failed to consider how

that increased use of Roundup, perhaps doubling its use on alfalfa fields in California alone, will impact the environment. And, argue plaintiffs, APHIS should have considered this increased use in the context of its deregulation of other Roundup Ready crops; in other words, APHIS must inquire whether the introduction of the many Roundup Ready crops will together increase the use of Roundup and impact the environment.

APHIS responds that there are other federal agencies, primarily the Environmental Protection Agency ("EPA"), that are responsible for regulating herbicides and tolerance levels in crops for such chemicals. It also contends that there is no evidence that farmers will misuse Roundup, that is, use it contrary to the manufacturer's instructions and it notes that Roundup use will replace more toxic herbicides.

Since the Court has concluded that APHIS must consider the cumulative impact of increased glyphosate use with respect to the development of glyphosate-resistant weeds, APHIS will have to examine the increased use of glyphosate; thus, the Court declines to specifically rule on this claim. The Court notes, however, that it is unclear from the record whether any federal agency is considering the cumulative impact of the introduction of so many glyphosate resistant crops; one would expect that some federal agency is considering whether there is some risk to engineering all of America's crops to include the gene that confers resistance to glyphosate.

C. Standing

The government contends that plaintiffs lack standing to bring their NEPA claims. While a court must ordinarily address the question of standing first,

in this case the question of standing is inextricably intertwined with the merits and the Court's discussion above demonstrates why plaintiffs have standing.

Article III standing requires "that the plaintiff show (1) an injury in fact that is both (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) that the injury is fairly traceable to the challenged action of the defendant; and (3) a likelihood that the injury will be redressed by a favorable decision." Ashley Creek Phosphate Co., 420 F.3d at 937.

The government argues that plaintiffs have not shown injury in fact for two reasons. First, it repeats its argument that economic interests do not fall "within NEPA's zone of interests." Gov't Reply at 6 (quoting Ashley Creek Phosphate Co., 420 F.3d at 938, 940). As the Court explained, supra, however, economic interests that are interrelated with natural or physical environmental effects fall within NEPA's zone of interests. The alfalfa farmer plaintiffs' potential economic injury arises directly from the environmental impact of APHIS's decision to deregulate Roundup Ready alfalfa. In Ashley Creek, in contrast, the plaintiffs' economic injury arose from increased competition, not from any environmental impact. Id. at 940.

Second, the government complains that plaintiffs have not shown a sufficient "geographic nexus" because they do not offer evidence that they farm near a genetically engineered alfalfa crop. The deregulation decision was made only recently, however, and at oral argument plaintiffs explained that the planting of the genetically engineered crop will occur in the spring; thus, it is premature for plaintiffs to show such injury.

Plaintiffs need not wait until the genetically engineered alfalfa is planted near their alfalfa fields to bring suit, or until their fields are contaminated with genetically engineered seed mixed with non-engineered seed. "[T]o require actual evidence of environmental harm, rather than an increased risk based on a violation of the statute, misunderstands the nature of environmental harm and would undermine the policy of the . . . Act." Central Delta Water Agency v. United States, 306 F.3d 947, 948 (9th Cir. 2002). "[T]he possibility of future injury may be sufficient to confer standing on plaintiffs; threatened injury constitutes 'injury in fact.'" Id. at 947. As is explained above, plaintiffs have established a "reasonable probability" that their organic and conventional alfalfa crops will be infected with the engineered gene, especially given the undisputed concentration of alfalfa seed farms. They have also established the reasonable probability of the development of additional glyphosate resistant weeds. Such threatened injury is sufficient to confer standing. The law does not require plaintiffs to meet the impossible task of proving that their alfalfa farms have already been contaminated. See Citizens for Better Forestry v. U.S. Dep't of Agriculture, 341 F.3d 961, 971-72 (9th Cir. 2003) ("Were we to agree . . . that a NEPA plaintiff's standing depends on 'proof' that the challenged federal project will have particular environmental effects, we would in essence be requiring that the plaintiff conduct the same environmental investigation that he seeks in his suit to compel the agency to undertake.") (internal quotation marks and citation omitted).

Finally, at oral argument the Court asked the government who would have standing if, as it asserts,

even the organic and conventional alfalfa farmers do not. The government responded that in its view no one has standing to challenge the deregulation decision in light of APHIS's finding that the engineered gene is harmless. As the Court explained, supra, it does not agree with APHIS's cramped reading of what constitutes an environmental impact.

II. OTHER CLAIMS

Since the Court has concluded that APHIS must prepare an EIS before approving the petition to deregulate Roundup Ready alfalfa, it need not address plaintiffs' claims under the ESA and PPA. The agency's decision may be different after it gathers the relevant data and considers the public's comments on such data; accordingly, the Court will not now decide the additional grounds for challenging the agency's decision. See Thomas v. Petersen, 753 F.2d 754, 761 n.4 (9th Cir. 1985). Plaintiffs' ESA and PPA claims are therefore dismissed without prejudice.

CONCLUSION

NEPA "is our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a). "NEPA emphasizes the importance of coherent and comprehensive up-front environmental analysis to ensure informed decision making to the end that 'the agency will not act on incomplete information, only to regret its decision after it is too late to correct.'" Blue Mountains Biodiversity Project, 161 F.3d at 1216 (quoting Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 371 (1989)). "An EIS is required of an agency in order that it explore, more thoroughly than an EA, the environmental consequences of a proposed action whenever 'substantial questions are raised as to whether a project *may* cause significant

[environmental] degradation." Id. (internal quotation marks and citation omitted).

"That is exactly the circumstances of this case." Id. Substantial questions are raised as to whether (1) the deregulation of Roundup Ready alfalfa without any geographic restrictions will lead to the transmission of the engineered gene to organic and conventional alfalfa; (2) the possible extent of such transmission; and (3) farmers' ability to protect their crops from acquiring the genetically engineered gene. Substantial questions are also raised as to the extent to which Roundup Ready alfalfa will contribute to the development of Roundup-resistant weeds, especially when considered in conjunction with the already deregulated and soon-to-be deregulated Roundup Ready crops, and as to how farmers will address such weeds. APHIS failed to answer these substantial questions, concluding instead that any environmental impact is insignificant because gene transmission is the problem of the organic and conventional farmers and weeds always develop resistance to herbicides. As such reasons are not "convincing" and do not demonstrate that the agency took a "hard look" at the potential environmental impacts of its deregulation decision, plaintiffs' motion for summary judgment on its NEPA claim that APHIS is required to prepare an EIS is GRANTED. Defendants' cross motion on the NEPA claim is DENIED, and the parties' cross-motions on the other claims are dismissed as moot in light of the Court's dismissal of those claims without prejudice.

The parties shall meet and confer and submit a proposed Judgment to the Court on or before February 26, 2007.

IT IS SO ORDERED.

Dated: Feb. 13, 2007

/s/
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON FARMS, INC., et al.,	No. C 06-01075 CRB
Plaintiffs,	**PRELIMINARY INJUNCTION**
v.	**ORDER**
MIKE JOHANNS, et al.,	
Defendants.	/

By Memorandum and Order dated February 13, 2007, the Court concluded that the federal defendants violated the National Environmental Protection Act ("NEPA") by failing to prepare an environmental impact statement ("EIS") before deregulating Roundup Ready alfalfa. The Court granted plaintiffs' motion for summary judgment because of the potential significant environmental impact of gene transmission; specifically, the acknowledged risk that the genetically engineered gene will "contaminate" organic and conventional alfalfa. The Court also found that defendants had failed to adequately consider the deregulation decision's impact on the development of Roundup resistant weeds.

The parties subsequently submitted competing proposed final judgments, and several third parties moved to intervene in the remedial phase of this lawsuit. At a hearing on March 8, 2007, the Court granted the proposed intervenors' motions and agreed to give them the opportunity "to present evidence to assist the court in fashioning the appropriate scope of whatever relief is granted." Forest Conservation Council v. U.S. Forest Service, 66 F.3d 1489, 1496 (9th

Cir. 1995). The immediate dilemma, however, is what preliminary relief to issue while the Court is contemplating the form of the final judgment. The issue is especially urgent because many growers have already planted or are about to plant Roundup Ready alfalfa.

A. The preliminary injunction

"In the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured." Idaho Watersheds Project v. Hahn, 307 F.3d 815, 833 (9th Cir. 2002); see also National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 737-38 & n.18 (9th Cir. 2001) (holding that "where an EIS is required, allowing a potentially environmentally damaging project to proceed prior its preparation runs contrary to the very purpose of the statutory requirement;" however, "in 'unusual circumstances' an injunction may be withheld, or, more likely, limited in scope"); Forest Conservation Council, 66 F.3d at 1496 (holding that the defendants "should be allowed to present evidence to the court that 'unusual circumstances' weigh against the injunction sought"); Thomas v. Peterson, 753 F.2d 754, 764 (9th Cir.1985) (stating that "absent 'unusual circumstances,' an injunction is the appropriate remedy for a violation of NEPA's procedural requirements").

One circumstance that makes this case not so "run of the mill" is that in reliance on the federal defendants' June 2005 deregulation decision, some growers have already planted Roundup Ready alfalfa. These plantings have occurred because plaintiffs did not seek an injunction prior to the Court's ruling on the merits of their claim. After weighing the balance of harms,

the Court will not order these growers to remove the alfalfa, and, indeed, plaintiffs do not ask for such injunctive relief. Nor will the Court prohibit these growers from harvesting, using, or selling any Roundup Ready alfalfa that has already been planted. See Seattle Audubon Soc'y v. Evans, 771 F.Supp. 1081, 1087-95 (W.D. Wash.1991) (taking logging industry interests into account in conducting equitable balancing for environmental law violation, resulting in injunction of future timber sales, but not existing sales), aff'd, 952 F.2d 297, 298 (9th Cir. 1991).

In most respects, however, this is a "run of the mill" NEPA case. Prior to the federal defendants' June 2005 deregulation decision, Roundup Ready alfalfa could not be grown absent a United States Department of Agriculture permit. For those growers who have not yet planted Roundup Ready alfalfa, or who intend to plant additional acres of the crop, an injunction prohibiting the planting of the genetically engineered crop pending the federal defendants' completion of the EIS, or at least pending the Court's fashioning of permanent injunctive relief, simply delays the project–in this case, delays the switch to Roundup Ready alfalfa. In other words, an injunction prohibiting future plantings maintains the status quo.

Neither the intervenors nor the government has identified any "unusual circumstances" that would warrant allowing an *increase* in the number of acres planted with Roundup Ready alfalfa while the Court considers the scope of permanent injunctive relief. At oral argument the Court asked counsel for the intervenor growers what harm farmers would suffer if the Court enjoined the *future* planting of alfalfa. Counsel responded that some growers might have

already purchased the seeds for planting, and thus would lose their investment, although he could not answer whether the growers would ultimately be reimbursed for such loss by insurance or the sellers. After the hearing the intervenors submitted an additional declaration opining that the growers do not have any contractual right to reimbursement. Counsel also explained that an injunction would prevent these growers from planting the alfalfa variety of their choice. An injunction, however, always prevents someone from doing what he would prefer, whether it be building a dam, completing a highway project, or planting a genetically engineered crop; the growers' disappointment in the delay to their switch to Roundup Ready alfalfa is not an interest which outweighs the potential environmental harm identified in the Court's February 13, 2007 Memorandum and Order. See National Parks & Conservation Ass'n, 241 F.3d at 737 ("When the proposed project may significantly degrade some human environmental factor, injunctive relief is appropriate").

Defendants and intervenors also complain that an order prohibiting an increase in the acreage of Roundup Ready alfalfa, that is, prohibiting any future plantings, will cause those growers who are about to plant such alfalfa "to scramble to make last-minute changes to farm planting plans and to find appropriate seed." See Second Declaration of Mark H. McCaslin ¶ 4. It bears repeating that these are growers who are *replacing* conventional alfalfa with Roundup Ready alfalfa; as the intervenors conceded at oral argument, alfalfa is a perennial crop that is only planted every three to four years. Thus, these growers' primary

experience is with non-genetically engineered alfalfa varieties.

In any event, to minimize the harm to those growers who intend to imminently plant Roundup Ready alfalfa, the Court will preliminarily enjoin all future planting of Roundup Ready alfalfa beginning **March 30, 2007**. Those growers who intend to plant Roundup Ready alfalfa in the next three weeks, *and have already purchased the seed*, may plant the seed. All growers intending to plant after March 30, 2007, or who have not yet purchased the seed, must plant non-genetically engineered alfalfa.

Accordingly, the federal defendants' June 2005 decision deregulating Roundup Ready alfalfa is VACATED and Roundup Ready alfalfa is once again a regulated article. The federal defendants shall issue the appropriate notices notifying Roundup Ready alfalfa sellers and growers that no Roundup Ready alfalfa seed may be planted after March 30, 2007. In addition, only that seed which has already been purchased by growers may be planted prior to March 30, 2007. All sales of Roundup Ready alfalfa seed are prohibited pending the Court's issuance of permanent injunctive relief.

B. Permanent Injunctive Relief

Before determining the scope of the final judgment, the Court will consider whatever additional evidence the intervenors wish to provide. All such evidence, and any supplemental supporting memoranda, must be filed on or before March 23, 2007. If the government wishes to submit additional evidence or a further memorandum, it must do so by the same date. Plaintiffs' response, if any, must be filed by April 6, 2007. The Court will hear oral argument on the

appropriate permanent injunctive relief at 11:00 a.m. on Friday, April 27, 2007. The Court will advise the parties prior to the hearing if any live testimony is required. The Court is not ordering any discovery.

IT IS SO ORDERED.

Dated: March 12, 2007

s/ Charles R. Breyer
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON FARMS INC., et al., Plaintiffs, v. MIKE JOHANNS, et al., Defendants, and MONSANTO COMPANY, et al., Intervenor-Defendants. /	No. C-06-01075 CRB **MEMORANDUM AND ORDER RE: PERMANENT INJUNCTION**

By Memorandum and Order dated February 13, 2007, the Court concluded that the federal defendants violated the National Environmental Protection Act ("NEPA") by failing to prepare an environmental impact statement ("EIS") before deregulating alfalfa genetically engineered to resist the herbicide Roundup ("Roundup Ready alfalfa"). The Court held that an EIS is required because of the potential significant environmental impact of gene transmission; specifically, the acknowledged risk that the genetically engineered gene will "contaminate" organic and conventional alfalfa. The Court also found that the federal defendants had failed to adequately consider the deregulation decision's impact on the development of Roundup-resistant weeds.

Now pending before the Court are the parties' competing proposals for permanent injunctive relief, various motions to strike, the intervenors' motion to file a surreply, the motion of the American Farm Bureau Federation to file an amicus brief, and the

intervenors' motion for reconsideration of the preliminary injunction order. The motion to file a surreply and the motion to file an amicus brief are granted.

BACKGROUND

A. The NEPA Violation

The government, specifically, the Animal and Plant Health Inspection Service ("APHIS"), chose not to prepare an EIS before it deregulated Roundup Ready alfalfa; instead, it issued a "Finding of No Significant Impact" ("FONSI"), finding that the deregulation of Roundup Ready alfalfa would not have a significant environmental impact. The Court concluded that APHIS's "no significant environmental impact" finding was erroneous. February 13, 2007 Memorandum and Order "(NEPA Order").

APHIS's position before the Court is, or at least was, that "even if deregulation of Roundup Ready alfalfa could result in the elimination of all non-genetically engineered alfalfa–in other words, there would be no alfalfa grown in the United States that does not contain the engineered gene that confers tolerance to glyphosate–such a result would still not constitute a significant environmental impact because APHIS has determinated that the introduction of that gene to alfalfa is harmless to humans and livestock, that is, it is not toxic or pathogenic." Id. at 12. The Court rejected this reasoning and concluded that the contamination of conventional and organic alfalfa with the Roundup Ready gene is itself an impact that is harmful to the human environment. Id at 13-14.

Moreover, even though APHIS acknowledged that gene transmission could and had occurred with Roundup Ready alfalfa, it refused to analyze the likely

extent of such gene flow and how it could be eliminated, or at least minimized; that is, how Roundup Ready alfalfa could co-exist with conventional and organic alfalfa. APHIS instead reasoned that it is, in effect, the organic and conventional alfalfa growers' responsibility to ensure that the genetically-engineered traits from neighboring crops do not spread to their own crops. Id. at 8-9. APHIS also found that gene transmission is not likely to occur with forage as opposed to seed crops because forage fields are typically harvested before the seed matures. Id. at 9. The Court concluded that APHIS's failure to analyze the likely extent of gene flow and whether any measures could be effectively implemented to prevent such contamination did not demonstrate the "hard look" required by NEPA. Id. at 9-10. APHIS's conclusion as to forage crops was similarly inadequate given that it offered no evidence as to how often farmers are actually able to harvest their forage crops before seed matures and it made no inquiry into the likelihood of gene transmission when, due to weather, they cannot. Id. at 10.

APHIS had also acknowledged that the deregulation of Roundup Ready alfalfa could result in the development of Roundup-resistant weeds, but in the FONSI it nevertheless found this risk was not "significant" because the development of herbicide-resistant weeds is common and "the agricultural community is addressing the issue." Id. at 15. The Court held that this analysis, too, is not the "hard look" NEPA requires. Id.

B. Procedural History

After the Court granted plaintiffs' motion for summary judgment and ordered the parties to address

an appropriate remedy, it granted the motions to intervene brought by the following: Monsanto Company ("Monsanto"), the owner of the intellectual property rights in Roundup Ready alfalfa; Forage Genetics Inc. ("Forage Genetics"), a Monsanto licensee and the exclusive developer of Roundup Ready alfalfa seed; a Roundup Ready alfalfa seed farmer under contract with Forage Genetics; a California farmer who, among other crops, has planted 40 acres of Roundup Ready alfalfa for forage; and a dairy farmer with 300 acres planted with Roundup Ready alfalfa.

After considering legal and evidentiary submissions from all parties, including the intervenors, and having had the benefit of several hours of oral argument, the Court vacated APHIS's June 2005 deregulation decision and issued a preliminary injunction which maintains the status quo while at the same time allowing those farmers who had plans for the imminent planting of Roundup Ready alfalfa to proceed with their planting. In particular, the Court allowed all Roundup Ready alfalfa which had been planted since APHIS's deregulation decision to be grown, harvested, and sold without restriction, but it preliminarily enjoined all future planting of Roundup Ready alfalfa beginning March 30, 2007. The delay allowed those growers who had intended to plant Roundup Ready alfalfa during the three weeks following the preliminary injunction order, and had already purchased the seed, to plant the genetically-engineered seed. All future sales of Roundup Ready alfalfa seed and post-March 30, 2007 plantings of Roundup Ready alfalfa were prohibited pending the Court's issuance of permanent injunctive relief. The Court also scheduled

a hearing on the scope of the permanent injunctive relief.

The parties have filed voluminous submissions as to permanent relief. Plaintiffs seek an order maintaining the status quo: the future planting of Roundup Ready alfalfa is enjoined pending the preparation of an EIS and APHIS's decision on Monsanto's deregulation petition. They also seek to enjoin the harvesting of any previously-planted Roundup Ready alfalfa seed and to require the publication of information as to the location of current Roundup Ready alfalfa crops.

APHIS and the intervenors (collectively "defendants") oppose the maintenance of the status quo; instead, they seek a remedy that facilitates the continued and dramatic growth of the Roundup Ready alfalfa market. There are currently approximately 200,000 acres planted with Roundup Ready alfalfa for forage and another 20,000 acres planted for seed. Intervenors estimate that absent plaintiffs' proposed injunction the acreage of Roundup Ready alfalfa planted for forage will increase to more than a million acres by 2008, a five-fold increase, and there will be a proportional increase in the number of acres planted for seed. Mark McCaslin March 23 Direct Testimony at 13. Defendants' seek, in effect, a partial deregulation that permits the continued expansion of the Roundup Ready alfalfa market subject to certain conditions. Specifically, APHIS proposes to require isolation distances between Roundup Ready alfalfa crops and alfalfa seed production fields; to prohibit pollinators from being added to Roundup Ready alfalfa fields; and to require that Roundup Ready alfalfa growers identify and keep records of all alfalfa crops being grown within 500 feet of their fields. APHIS also proposes to require

specific harvesting conditions for Roundup Ready alfalfa fields to minimize gene flow in areas where growers are producing non-genetically engineered alfalfa seeds, including specifying when the fields must be harvested. Finally, farm equipment used in Roundup Ready alfalfa production must be properly cleaned after use and Roundup Ready alfalfa must be handled and identified to minimize commingling after harvest.

LEGAL STANDARD

Upon a finding of a NEPA violation an injunction does not automatically issue; "injunctive relief is an equitable remedy, requiring the court to engage in the traditional balance of harms analysis, even in the context of environmental litigation." Forest Conservation Council v. U.S. Forest Service, 66 F.3d 1489, 1496 (9th Cir. 1995); see also National Parks & Conservation Ass'n. v. Babbitt, 241 F.3d 722, 737 (9th Cir. 2001) ("To determine whether injunctive relief is appropriate, 'even in the context of environmental litigation,' we apply 'the traditional balance of harms analysis.'") (internal citation omitted). "[I]n the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured," that is, the balance of harms favor issuance of an injunction. Idaho Watersheds Project v. Hahn, 307 F.3d 815, 833 (9th Cir. 2002); see also National Parks & Conservation Ass'n., 241 F.3d at 737 (holding that "where an EIS is required, allowing a potentially environmentally damaging project to proceed prior to its preparation runs contrary to the very purpose of the statutory requirement"). An injunction is appropriate because "[e]nvironmental injury, by its nature, can seldom be

adequately remedied by money damages and is often permanent or at least of long duration, i.e., irreparable." National Parks & Conservation Ass'n., 241 F.3d at 737 (internal quotation marks and citation omitted); see also High Sierra Hikers Association v. Blackwell, 390 F.3d 630, 642 (9th Cir. 2004) ("the presence of a strong NEPA claim gives rise to more liberal standards for granting an injunction") (internal quotation marks and citation omitted).

The Ninth Circuit has nevertheless recognized that "in 'unusual circumstances' an injunction may be withheld, or, more likely, limited in scope." National Parks & Conservation Ass'n., 241 F.3d at 737 n.18; see also Forest Conservation Council, 66 F.3d at 1496 (holding that the defendants "should be allowed to present evidence to the court that 'unusual circumstances' weigh against the injunction sought").

DISCUSSION

A. An Injunction Against the Continued Growth of the Roundup Ready Alfalfa Market

The Court's preliminary injunction order maintained the status quo by prohibiting any planting of Roundup Ready alfalfa after March 30, 2007. Defendants ask the Court to permit the continued dramatic expansion of the Roundup Ready alfalfa market pending APHIS's preparation of the legally-required EIS, provided certain conditions are met. In support of their proposal, defendants offer evidence from several experts, as well as employees of the intervenors, opining that if the isolation distances and other conditions are satisfied, the risk of gene flow is so small as to be outweighed by the harm to Monsanto, Forage Genetics, seed distributors, and farmers who want to plant Roundup Ready alfalfa. As they

explained at oral argument, they contend that in light of these proposed conditions, plaintiffs have not demonstrated irreparable harm and therefore a blanket prohibition on future plantings is not warranted.

After carefully reviewing defendants' voluminous evidence, including the evidence submitted in support of the intervenors' surreply, as well as plaintiffs' evidence, the Court declines to permit the expansion of the Roundup Ready alfalfa market while APHIS conducts the analysis it should have prepared before it allowed for the non-permitted introduction of the crop in the first instance.

In holding that APHIS violated NEPA, the Court concluded that APHIS had failed to adequately analyze the risk of gene flow and to what extent, if any, certain measures could be implemented to effectively prevent such contamination. Although APHIS has represented that it will take it approximately two years to prepare an EIS, it contends that during the month following this Court's summary judgment order it has conducted analysis sufficiently adequate to conclude that if its proposed conditions are imposed by the Court, gene flow will not occur, at least not in any significant respect, and therefore the Court should permit the expansion of the Roundup Ready alfalfa market pending APHIS's preparation of an EIS. The Court is not persuaded.

The intervenors have requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses. Plaintiffs and intervenors have also moved

to strike much of the opposing parties' evidence on various grounds, including that a particular witness is not qualified to give the opinion stated.

To make the findings requested by defendants would require this Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS; defendants are in effect asking this Court to accept its truncated EIS without the benefit of the development of all the relevant data and, importantly, without the opportunity for and consideration of public comment. See The Lands Council v. Powell, 395 F.3d 1019, 1027 (9th Cir. 2005) ("The purpose of NEPA is to require disclosure of relevant environmental considerations that were given a 'hard look' by the agency, and thereby to permit informed public comment on proposed action and any choices or alternatives that might be pursued with less environmental harm."). "[D]etermining what measures are needed through extensive fact intensive inquiry is precisely the purpose of the long term environmental review ordered by [the Court]." Idaho Watersheds Project, 307 F.3d at 83. As the Ninth Circuit has observed,

> it would be odd to require the district court to conduct an extensive inquiry, which would by nature involve scientific determinations, in order to support interim measures that are designed to temporarily protect the environment while the [government] conducts studies in order to make the very same scientific determinations.

Id. Yet, defendants ask the Court to now conduct—based on a limited record—the very same scientific inquiry it ordered APHIS to do as part of the EIS process.

APHIS contends, in essence, that it can grant Monsanto's deregulation petition without preparation of an EIS as long as it imposes certain conditions on the introduction of the genetically-engineered crop. For example, APHIS's Director of Environmental Risk Analysis Division represents that APHIS "is fully committed to preparing a comprehensive environmental impact statement (EIS) prior to deciding in the future whether [Roundup Ready Alfalfa] should be *unconditionally* deregulated." Second Declaration of Neil Hoffman (March 7, 2007) ¶ 2 (emphasis added). Hoffman's carefully chosen words reveal that APHIS is *not* committed to preparing an EIS before it conditionally deregulates Roundup Ready alfalfa, which is what it is attempting to do with its proposed permanent relief.

The Court rejects APHIS's cramped reading of this Court's Order and NEPA. APHIS's decision on Monsanto's deregulation petition is the major federal action requiring the preparation of an EIS; APHIS does not need to prepare an EIS only if it ultimately decides to *unconditionally* deregulate the genetically engineered crop. As the Court found in its NEPA Order, it is the significant threat of gene flow and the development of Roundup-resistant weeds that requires further study and analysis in an EIS so that APHIS can decide if deregulation is appropriate and, if so, under what, if any, conditions. NEPA Order at 10. The Court never suggested that APHIS could skip the EIS process and decide without any public comment that deregulation with certain conditions is appropriate.

In any event, defendants' analysis is still inadequate. They have not submitted any evidence

that suggests whether, and to what extent, the proposed interim conditions will be followed, even though such conditions are similar to those already imposed by Forage Genetics in its contracts with Roundup Ready seed growers and contamination has occurred despite those conditions. Defendants simply respond that the government has the authority to enforce the conditions, but having the authority and effectively using the authority are two different matters: the government has the authority to enforce the immigration laws, but unlawful entry into the United States still occurs. Moreover, APHIS asserts that it does not have the resources to inspect the 220,000 acres currently planted with Roundup Ready alfalfa hay. Second Declaration of Neil Hoffman (March 7, 2007) at ¶ 3. It does not explain how it expects to have the resources to adequately monitor the more than one million acres of Roundup Ready alfalfa hay intervenors estimate will be planted, and the concomitant increase in seed acreage, if, as they urge, the Court does not prohibit future plantings.

Another example of the continued inadequacy of defendants' analysis is their contention that requiring growers to harvest their crops before seed sets or before ten percent bloom will virtually eliminate any chance of contamination. In its NEPA Order the Court noted that the government had "failed to consider . . . that because of weather–which is beyond a farmer's control–a farmer cannot always harvest his field at the most optimal time." NEPA Order at 10. APHIS has still not made any inquiry (that it has shared with the Court) into "how often farmers are actually able to harvest their forage crop before seeds mature and no inquiry into the likelihood of gene transmission when

they cannot." *Id.* Indeed, at oral argument on the preliminary injunction, the Court asked Mark McCaslin, the President of Forage Genetics, whether the Court should enter an order requiring harvest at a certain point to reduce the likelihood of gene flow. Mr. McCaslin candidly responded: "In the midwest where there is no seed production, that would be a disaster because there is–the challenge in the midwest is usually harvesting around the weather." March 8, 2007 Transcript at 27.

With this context in mind, the Court finds that plaintiffs have sufficiently established irreparable injury and that the balance of the equities weighs in favor of maintenance of the status quo and against allowing the continued expansion of the Roundup Ready alfalfa market pending the government's completion of the EIS. As the Court explained in its NEPA Order, contamination of organic and conventional alfalfa crops with the genetically engineered gene has occurred and defendants acknowledge as much. Such contamination is irreparable environmental harm. The contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa. Moreover, it is not a one season loss; alfalfa is a perennial crop and once removed cannot be replanted for two to four years. Mark McCaslin March 23, 2007 Direct Testimony at 6.

The harm to these farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa. Roundup Ready alfalfa is only 15 percent of Forage

Genetics' total revenue and much, much less of Monsanto's. Moreover, intervenors do not contend that the harvested but unsold seed cannot be stored until–and if–APHIS decides to deregulate Roundup Ready alfalfa after conducting an objective and thorough environmental analysis. The loss of anticipated revenue to Monsanto and Forage Genetics in the meantime "does not outweigh the potential irreparable damage to the environment." National Park & Conservation Ass'n., 241 F.3d at 738. Moreover, neither Monsanto nor Forage Genetics "have cause to claim surprise as a result of any injunction." *Id.* They were aware of plaintiffs' objections to the deregulation decision at the time it was made and were aware of plaintiffs' lawsuit; they nonetheless chose to market Roundup Ready alfalfa.

The desire of some farmers to plant *more* Roundup Ready alfalfa or to *switch to* Roundup Ready alfalfa, that is, to do something different from what they have done in the past, similarly does not outweigh the potential for irreparable harm. And if these farmers were not aware of the plaintiffs' challenge to Roundup Ready alfalfa, that is a matter to raise with Monsanto and Forage Genetics. See National Park & Conservation Ass'n., 241 F.3d at 738 (noting that cruise ship passengers who were not warned by carrier of lawsuit challenging cruises "were not well served by that company").

Allowing an expansion of the Roundup Ready alfalfa market pending the preparation of the EIS would be unprecedented. None of the cases cited by defendants allowed for an *increase* in the activity that posed the risk to environment. In Idaho Watersheds Project, for example, the district court found that the

Bureau of Land Management had violated NEPA by issuing permits for cattle grazing without preparing the required environmental documentation. The district court considered and rejected a complete halt to all grazing, concluding that such a remedy would be too drastic. Id. at 833. Instead, the court allowed the previously-permitted grazing to continue pending the BLM's completion of its environmental review, subject to certain conditions designed to mitigate the harm from the continued grazing. Id. The court did not, however, allow the BLM to issue additional permits, which is essentially what defendants ask for here. The "middle ground" taken by the court in Idaho Watersheds is the approach taken here: as will be discussed below, the Court is not requiring those farmers who have already planted Roundup Ready alfalfa to destroy their crops; instead, the Court is prohibiting the introduction of any new Roundup Ready crops.

In High Sierra Hikers Association, another case cited by defendants, the court held that the government violated NEPA by issuing multi-year special-use permits to commercial outfitters and guides in the John Muir and Ansel Adams wilderness areas without first preparing and EIS. 390 F.3d at 640-41. The court did not require the permitted packers to cease operations; instead, the court crafted a remedy that allowed for the continued operations of the packers, provided the current levels of use were reduced by 20 percent. Id. at 642-43. Again, the court did not allow for the packers' operations to increase–or for new permits to be issued; to the contrary, the court reduced the level of commercial pack operations. Here, in contrast, defendants seek to *dramatically increase*

the amount of acres planted with Roundup Ready alfalfa even though the Court has ruled that the government should have prepared an EIS before allowing the plantings in the first place. See also Sierra Club v. Penfold, 857 F.2d 1307, 1316-17 (9th Cir. 1988) (allowing mining operations begun prior to court's finding of NEPA violation to be completed, but prohibiting any additional mining operations); Northern Cheyenne Tribe v. Hodel, 851 F.2d 1152, 1154-55, 1157-58 (9th Cir. 1988) (after finding that government awarded mining leases three years earlier in violation of NEPA, the district court suspended the mining operations in all but two of the mines; the Ninth Circuit held that the district court had discretion to balance the equities to allow the mining operations to continue, although it had done so on an inadequate record, but the court did not allow for an increase in mining); Westlands Water Dist. v. U.S. Dept. of Interior, 275 F. Supp. 2d 1157 (E.D. Cal. 2002) (enjoining part of project, but allowing part of project to continue in light of a congressional mandate; court did not allow for an increase in the project pending completion of the environmental review); Wilderness Watch v. U.S. Forest Service, 143 F. Supp. 2d 1186 (D. Mont. 2000) (court refused to order the destruction of wilderness lodge built without the required environmental assessments; court did not allow for the future construction of lodges while the environmental review was pending).

Finally, the Court rejects defendants' assertion that allowing an expansion in the Roundup Ready alfalfa market is in the public interest because it promotes the use of less toxic herbicides. The record reflects that organic and most conventional forage alfalfa is grown

without the use of any herbicides. In any event, a finding that increasing the use of Roundup is in the public interest is premature in light of APHIS's failure to analyze the potential for the development of Roundup-resistant weeds. Moreover, it is not in the public interest to take action that has the potential of eliminating the availability of a non-genetically engineered crop without adequate investigation into the long term impact of such action; rather, the Court finds that it is in the public interest to delay the further introduction of Roundup Ready alfalfa into the environment while APHIS studies the environmental consequences of such action.

In sum, after balancing all of the equities, the Court in its discretion finds that an injunction maintaining the status quo by prohibiting the planting of Roundup Ready alfalfa after March 30, 2007 is appropriate. The Court cautions that it does not intend its injunction to apply to plantings of Roundup Ready alfalfa as a regulated article under permit from APHIS. While some lawsuits have challenged APHIS's permitting process for regulated articles, see, e.g., Int'l Center for Technology Assessment v. Johanns, 473 F.Supp.2d 9 (D.D.C. 2007), this lawsuit challenges APHIS's action on Monsanto's deregulation petition. And plaintiffs have not established that APHIS will avoid the import of this Court's injunction by abusing the permit process. APHIS has represented under oath that its current permitting process is designed to regulate small scale field tests and that it does not have the resources to provide permits for and adequately monitor large acreage of Roundup Ready alfalfa. Second Declaration of Neil Hoffman (March 7, 2007) ¶ 3.

B. Already Planted Roundup Ready Alfalfa

As the Court noted in its preliminary injunction order, some growers have already planted Roundup Ready alfalfa in reliance on the federal defendants' June 2005 deregulation decision. Plaintiffs do not seek to enjoin such forage alfalfa from being grown, harvested and sold, and the Court agrees that such a remedy would be too drastic, especially in light of the Court's order capping the number of acres of Roundup Ready alfalfa. See Seattle Audubon Soc'y v. Evans, 771 F.Supp. 1081, 1087-95 (W.D. Wash. 1991) (taking logging industry interests into account in conducting equitable balancing for environmental law violation, resulting in injunction of future timber sales, but not existing sales), aff'd, 952 F.2d 297, 298 (9th Cir. 1991).

Plaintiffs do seek to enjoin the harvesting and sale of already planted Roundup Ready alfalfa seed. They contend that the risk of contamination from the mixing of the genetically-engineered seed with non-engineered seed outweighs any harm to those farmers with contracts with Forage Genetics to produce such seeds. The Court declines to impose such an order and interfere with the contracts entered into by these farmers. The record reflects that Forage Genetics has contracts with 76 farmers to grow Roundup Ready alfalfa seed. The financial burden to these farmers of an injunction preventing them from fulfilling their contracts outweighs the harm to the human environment in these limited circumstances. See Amoco Production Co. v. Gambell, 480 U.S. 531, 541, 544-45 (1987) (noting, in summarizing Ninth Circuit law, that "unusual circumstances" weighing against injunctive relief include "those in which an injunction would interfere with a long-term contractual

relationship"); Sierra Club, 857 F.2d at 1316-17 (allowing mining operations begun prior to court's finding of NEPA violation to be completed, but prohibiting any additional mining operations).

The Court will impose certain conditions in an attempt to minimize the risk of gene flow from the already-planted genetically engineered alfalfa to organic and conventional alfalfa. As the alfalfa has already been planted, the Court will not impose isolation distances; however, the Court will adopt the relevant conditions proposed by APHIS. In particular, within 45 days of the date of this Order, APHIS shall issue an administrative order imposing the following requirements:

I. Pollinators shall not be added to Roundup Ready alfalfa fields grown only for hay production.

II. Farm equipment used in Roundup Ready alfalfa production shall be properly cleaned after use.

   A. Cleaning procedures for harvesters, tractors and tillage equipment shall be submitted to and approved by APHIS prior to implementation.

   B. Cleaning procedures shall be designed to minimize the risk of Roundup Ready alfalfa seed and hay movement from authorized production site.

   C. All equipment shall be cleaned in accordance with the approved procedures before it leaves the farm on which in came in contact with Roundup Ready alfalfa.

III. Roundup Ready alfalfa shall be handled and clearly identified to minimize commingling

> after harvest. Immediately after harvest, growers or seed producers shall store Roundup Ready alfalfa in specifically designated and clearly labeled containers.

As all Roundup Ready seed growers are under contract with Forage Genetics, and as all Roundup Ready alfalfa farmers have a license with Monsanto, Monsanto, Forage Genetics and APHIS shall work together to ensure that all Roundup Ready alfalfa farmers are aware of the above requirements.

It is also important that the organic and conventional alfalfa farmers learn where Roundup Ready alfalfa is grown so that they can test their own crops to determine if there has been contamination. Forage Genetics maintains GPS or plat mats identifying the location of all alfalfa seed production acreage. Mark McCaslin March 23 Direct Testimony at 9. Forage Genetics also requires growers who purchase Roundup Ready alfalfa in 17 Western states to provide field size and GPS locations at the time of purchase "to enable monitoring and enforcement of the Monsanto trait stewardship measures." Id. at 16. Within 30 days of the judgment, Forage Genetics shall provide the above identifying information to APHIS and APHIS shall make such information publicly available as soon as practicable, including, but not limited to, making such information available on the appropriate government website. Forage Genetics shall also use its best efforts to obtain field size and GPS locations of Roundup Ready alfalfa in the remaining states and provide such information to APHIS for public disclosure.

CONCLUSION

For the reasons explained above, the intervenors' motion for reconsideration of the preliminary injunction order is DENIED. The Court will enter a final judgment (1) vacating the June 2005 deregulation decision; (2) ordering the government to prepare an EIS before it makes a decision on Monsanto's deregulation petition; (3) enjoining the planting of any Roundup Ready alfalfa in the United States after March 30, 2007 pending the government's completion of the EIS and decision on the deregulation petition; and (4) imposing the above conditions on the handling and identification of already-planted Roundup Ready alfalfa.

The parties shall jointly submit a written status report within 60 days of the date of this Order to update the Court on defendants' compliance with the injunction.

IT IS SO ORDERED.

Dated: May 3, 2007

/s/ Charles R. Breyer
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEERTSON SEED FARMS, an Oregon business; Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp., Plaintiffs-Appellees,

v.

Mike JOHANNS, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants,

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors,

and

Monsanto Company, Defendant-Intervenor-Appellant.

Geertson Seed Farms, an Oregon business; Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.;

Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp., Plaintiffs-Appellees,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants,

Monsanto Company, Defendant-Intervenor,

and

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors-Appellants.

Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp.; Geertson Seed Farms, an Oregon business, Plaintiffs-Appellees,

and

Geertson Seed Farms, an Oregon Corp., Plaintiff,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture; Defendants-Appellants,

and

Monsanto Company; Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors.

Nos. 07-16458, 07-16492, 07-16725.

Argued and Submitted June 10, 2008.
Filed Sept. 2, 2008.

541 F.3d 938

Before: MARY M. SCHROEDER and N. RANDY SMITH, Circuit Judges, and VALERIE FAIRBANK,* District Judge.

Opinion by Judge SCHROEDER; Dissent by Judge N. RANDY SMITH

SCHROEDER, Circuit Judge:

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* The Honorable Valerie Fairbank, United States District Judge for the Central District of California, sitting by designation.

The Monsanto Company ("Monsanto") is a large-scale manufacturer of chemical products, including herbicides and pesticides. In the 1990s it began developing a variety of alfalfa that would be resistant to one of its leading herbicides. The United States Department of Agriculture, through the Animal and Plant Health Inspection Service ("APHIS"), approved the genetically modified alfalfa in 2005.

This is an appeal from an injunction entered by the district court enjoining future planting of Monsanto alfalfa, called "Roundup Ready alfalfa," pending the preparation by APHIS of an environmental impact statement ("EIS"). The injunction was sought by plaintiffs Geertson Seed Farms and Trask Family Seeds, conventional alfalfa-seed farms, together with environmental groups, because they fear cross-pollination of the new variety with other alfalfa, thereby possibly causing conventional alfalfa to disappear. Monsanto and its licensee, Forage Genetics, Inc. ("Forage Genetics"), intervened on the side of the government defendants. Monsanto, Forage Genetics, and the government pursue this appeal.

There are no issues of law and we therefore review for abuse of discretion. *See Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 823 (9th Cir.2002). We affirm because the district court did not abuse its discretion in entering the injunction after holding one hearing on the nature of the violation of the National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. § 4332(C), and two hearings on the scope of injunctive relief, as well as reviewing extensive documentary submissions relating to an appropriate remedy. The injunction is limited in duration to the time necessary to complete the EIS.

The existence of the NEPA violation is not disputed on appeal.

Background

Roundup Ready alfalfa is an alfalfa crop that was genetically engineered by Monsanto to be tolerant of glyphosate, which is the active ingredient in its herbicide Roundup. The particular lines of genetically engineered alfalfa that are at issue here were designated as events J101 and J163 ("Roundup Ready alfalfa"). Monsanto owns the intellectual property rights to Roundup Ready alfalfa and licenses the technology to Forage Genetics, who is the exclusive developer of Roundup Ready alfalfa seed.

APHIS, a division of the United States Department of Agriculture, has the authority to regulate "the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," or "regulated articles." *See* 7 C.F.R. § 340.0(a)(2) & n. 1. APHIS initially classified Roundup Ready alfalfa as a regulated article. Monsanto submitted a petition in April 2004 requesting nonregulated status for events J101 and J163. APHIS had three options: it could take no action, in which case Roundup Ready alfalfa would continue to be a regulated article; it could unconditionally deregulate Roundup Ready alfalfa, which would require the agency to make a finding of no significant impact; or it could partially deregulate Roundup Ready alfalfa, either by approving some but not all of the lines involved, or by approving the petition but imposing geographic restrictions.

APHIS published a notice in the Federal Register in November 2004 advising the public of Monsanto's petition and soliciting comments. It explained that

APHIS had prepared an Environmental Assessment ("EA") in accordance with NEPA and its implementing regulations. In the EA, APHIS explained that alfalfa is pollinated by insects, primarily bees, and that insect pollination has been documented as occurring up to 2 miles from the pollen source. With regard to the threat of possible genetic contamination of non-genetically engineered alfalfa, it explained that the National Organic Program mandates buffer zones around organic production operations, the size of which are decided by the organic producer and the certifying agent on a case-by-case basis. The EA concluded that it was therefore unlikely that Roundup Ready alfalfa would have a significant impact on organic farming.

APHIS received 663 comments, 520 of which opposed the petition and 137 of which supported it. Most of the commenting alfalfa growers and seed producers supported it because they said there was a demand for weed-free alfalfa, and Roundup Ready alfalfa would provide farmers a new option for weed control by allowing farmers to apply herbicide after weeds have germinated. Most of the academic professionals, agricultural support industries, and growers associations who commented supported the petition as well. Opponents of the petition, who included organic and conventional alfalfa growers, cited concerns that inadvertent gene transmission would occur, and that foreign and domestic markets may not accept products that cannot be guaranteed to be non-genetically engineered. They urged a full environmental evaluation through an EIS that would analyze the environmental effects of all the alternatives. *See Natural Res. Def. Council, Inc. v. Winter*, 518 F.3d 658, 688 (9th Cir.2008) ("NEPA's

procedural requirements mandate that an agency take a 'hard look' at the environmental consequences of its actions.").

On the basis of the EA and after considering the comments received, APHIS in June 2005 made a finding of no significant impact. *See* 70 Fed.Reg. 36,917, 36,918 (June 27, 2005). It therefore concluded that it did not need to prepare an EIS, and it unconditionally deregulated Roundup Ready alfalfa.

Plaintiffs filed this action in February 2006, alleging violations of NEPA and other federal statutes. The district court first considered whether APHIS had violated NEPA. After a hearing on plaintiffs' and defendants' motions for summary judgment, the district court granted plaintiffs' motion in February 2007, holding that APHIS had violated NEPA by deregulating Roundup Ready alfalfa without first preparing an EIS. The court ruled APHIS had failed to take the required "hard look" at whether and to what extent the unconditional deregulation of Roundup Ready alfalfa would lead to genetic contamination of non-genetically engineered alfalfa. The district court then turned to the issue of an appropriate remedy for the violation.

Monsanto and Forage Genetics intervened in the action at the remedies phase. They argued that growers had already purchased Roundup Ready alfalfa seed in preparation for the spring planting season, which was underway and would be ending soon, and that it would be difficult for those growers to purchase other seed in time to plant it. After hearing argument, the court entered a preliminary injunction on March 12, 2007. The preliminary injunction enjoined all planting of Roundup Ready alfalfa and all sales of Roundup

Ready alfalfa seed after March 30, 2007, pending the issuance of a permanent injunction. This allowed farmers who were prepared to plant Roundup Ready alfalfa immediately, and who had already purchased the seed, to do so. The injunction also allowed all Roundup Ready alfalfa that had been planted since the deregulation decision to be grown, harvested, and sold without restriction.

In April 2007, the court held a hearing on the scope of permanent injunctive relief. Plaintiffs sought to enjoin all future planting of Roundup Ready alfalfa, as well as the harvesting of any Roundup Ready alfalfa seed already planted, pending the completion of an EIS and a new decision on deregulation; they also requested the publication of the location of Roundup Ready alfalfa crops. Defendants asked that planting go forward, but not unconditionally. At the remedy stage, APHIS agreed for the first time that any future planting should be subject to certain conditions, including requiring isolation distances from other crops and requiring certain harvesting conditions to minimize gene flow to non-genetically engineered alfalfa seeds.

The district court considered voluminous evidentiary submissions from both sides, including the detailed declarations of multiple witnesses regarding the scope of permanent injunctive relief and scientific papers on the factual issues involved. The parties' experts disagreed over virtually every factual issue, including the likelihood of genetic contamination and why some contamination had already occurred. Defendants' evidence included declarations and live testimony by Forage Genetics' president, Mark McCaslin, declarations of an APHIS official, Neil Hoffman, and a declaration from a scientist at Colorado

State University, Bob Hammon, who had conducted a study sponsored by Forage Genetics on pollen movement from alfalfa-seed fields by bees. Plaintiffs' evidence included Hammon's study, which they argued supports their position, as well as declarations from seed growers whose crops had been contaminated with the Roundup Ready gene and scientists who opined that genetic contamination is likely to occur.

The court entered its permanent injunction in May 2007. It enjoined all planting of Roundup Ready alfalfa after March 30, 2007, pending APHIS's completion of an EIS and decision on the deregulation petition. The district court rejected the conditions proposed by the agency because it found that genetic contamination had occurred when similar conditions were in place pursuant to Forage Genetics' contracts with its Roundup Ready alfalfa growers. Defendants, joined by intervenors Monsanto and Forage Genetics (collectively, "appellants"), now appeal the injunction, arguing it is too broad. Neither the government nor the intervenors now question the existence of a NEPA violation. They dispute only the scope of the injunction, and whether the district court should have held a further hearing.

Scope of the Permanent Injunction

Appellants argue that the district court erred in ordering injunctive relief because it improperly presumed irreparable injury instead of applying the traditional four-factor test for the issuance of a permanent injunction, as required under *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006). They argue that, as a result, the district court's injunction was overbroad because the court did not consider the likelihood of potential

harm if Roundup Ready alfalfa was planted subject to the mitigation measures proposed by APHIS.

To obtain permanent injunctive relief, a plaintiff must show " '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.' " *N. Cheyenne Tribe v. Norton*, 503 F.3d 836, 843 (9th Cir.2007) (quoting *eBay*, 547 U.S. at 391, 126 S.Ct. 1837). This traditional balancing of harms applies in the environmental context. *Forest Conservation Council v. U.S. Forest Serv.*, 66 F.3d 1489, 1496 (9th Cir.1995); *see also Lands Council v. McNair*, 537 F.3d 981, 1005, 2008 WL 2640001, at *21 (9th Cir.2008) (en banc) ("Our law does not ... allow us to abandon a balance of harms analysis just because a potential environmental injury is at issue."). In determining the scope of an injunction, a district court has " 'broad latitude,' " *High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 641 (9th Cir.2004) (quoting *Natural Res. Def. Council v. Sw. Marine, Inc.*, 236 F.3d 985, 999 (9th Cir.2000)), and it " 'must balance the equities between the parties and give due regard to the public interest,' " *N. Cheyenne Tribe*, 503 F.3d at 842-43 (quoting *High Sierra*, 390 F.3d at 642).

The Supreme Court has recognized that "the balance of harms will usually favor the issuance of an injunction to protect the environment" if injury is found to be sufficiently likely because "[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or

at least of long duration, *i.e.*, irreparable." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545, 107 S.Ct. 1396, 94 L.Ed.2d 542 (1987). In *Amoco*, the Court held that a preliminary injunction had been improperly ordered because injury to the environment was "not at all probable." *Id.* This court has recognized that even when a district court finds that a NEPA violation occurred, "in 'unusual circumstances' an injunction may be withheld, or, more likely, limited in scope." *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 737 n. 18 (9th Cir.2001) (citing *Forest Conservation Council*, 66 F.3d at 1496).

The Supreme Court held in *eBay* that courts cannot grant or deny injunctive relief categorically in place of applying the four-factor test. 547 U.S. at 394, 126 S.Ct. 1837. The district court in that case had suggested that patent holders who license their patents do not suffer irreparable harm. *Id.* at 393, 126 S.Ct. 1837. The Court held that the district court had erred in adopting "expansive principles suggesting that injunctive relief could not issue in a broad swath of cases." *Id.* It held that the reversing court of appeals had also erred because it too had applied a categorical rule, that injunctions in patent cases should generally be granted once infringement and validity are established except in the "unusual case, under exceptional circumstances." *Id.* at 394, 126 S.Ct. 1837 (internal quotation marks omitted). The Court held "that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity . . . ." *Id.*

Here, the record demonstrates that the district court applied the traditional four-factor test, required

by *eBay*, before issuing its injunction. It expressly recognized that an injunction does not "automatically issue" when a NEPA violation is found and said that it was required to "engage in the traditional balance of harms analysis." The court then discussed each of the four factors of the traditional balancing test and concluded that the equities favored an injunction against the future planting of Roundup Ready alfalfa.

With respect to harm, the court found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place that were similar to their proposed mitigation measures. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. The court also reasoned that appellants would be unable to enforce compliance with any proposed mitigation measures, given the government's admitted lack of resources. The court therefore did not presume that irreparable harm was likely to occur only on the basis of the NEPA violation; it concluded that plaintiffs had established that genetic contamination was sufficiently likely to occur so as to warrant broad injunctive relief, though narrower than the blanket injunction sought by plaintiffs.

Appellants contend the district court did not take into account the evidence demonstrating that the likelihood of hay-to-hay transmission is extremely low because hay is harvested before the crops bloom to 10%. The district court examined the evidence and found that weather conditions could prevent farmers from harvesting hay before 10% bloom, citing the

testimony of Forage Genetics' president. The district court's finding was not clearly erroneous.

After considering the likelihood of irreparable injury, the court next considered the balance of hardships. The harm to appellants was economic, and the court reasoned that Roundup Ready alfalfa accounted for only 15% of Forage Genetics' total revenue and "much, much less of Monsanto's." It also found that any unsold seed appears to be storable for planting in later years. The court's injunction allowed Roundup Ready alfalfa that had already been planted and that was to be planted before March 30 to remain, subject to certain conditions, and only enjoined future planting, which demonstrates that the court crafted a remedy that accounted for the hardships to both sides. Monsanto and Forage Genetics contend that the district court disregarded their financial losses, but the district court considered those economic losses and simply concluded that the harm to growers and consumers who wanted non-genetically engineered alfalfa outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The district court finally considered the public interest, the fourth factor in the framework for injunctive relief. *See N. Cheyenne Tribe*, 503 F.3d at 843. The court, while recognizing that agricultural biotechnology has social value, held that it would be in the public interest to enjoin the expanded use of Roundup Ready alfalfa before its impact was studied, because failing to do so could potentially eliminate the availability of non-genetically engineered alfalfa.

Appellants rely on *Northern Cheyenne* for the proposition that a narrower injunction should be entered here. In that case, we affirmed a district

court's injunction. *Id.* at 846. *Northern Cheyenne* does not support a reversal in this case. There, the Bureau of Land Management ("BLM") had violated NEPA because its EIS failed to study an alternative method of development that the plaintiffs wanted the BLM to consider. *See id.* at 841, 844. The injunction permitted one method to proceed and prohibited other activity pending full compliance with NEPA. *Id.* We held that the district court's injunction was not an abuse of discretion. That conclusion does not support a holding that the injunction in this case was an abuse of discretion. APHIS did not take the requisite "hard look" at the impact of any form of deregulation on the environment. *See Nat. Res. Defense Council*, 518 F.3d at 688.

Appellants also argue that the district court should have deferred to APHIS's proposed interim measures because of the expertise of the government agency, despite the agency's now undisputed failure to comply with NEPA. They rely primarily on *Idaho Watersheds Project*, 307 F.3d 815. However, that case does not require a district court to adopt an agency's proposed measures as a matter of law. In *Idaho Watersheds*, to determine the terms of an injunction to protect land and streams from the effects of too much cattle grazing pending the BLM's compliance with NEPA, the district court adopted the interim measures proposed by the BLM to respond to environmental injury, which the court thought represented a "balanced approach." *Id.* at 823, 830-31. Affirming, we said that "the Ninth Circuit has shown considerable deference for factual and technical determinations implicating substantial agency expertise." *Id.* at 831. Here, the agency's proposed interim measures would perpetuate a system

that was found by the district court to have caused environmental harm in the past. While the agency's response may deserve deference, *Idaho Watersheds* does not require the district court to adopt it automatically. The district court did not abuse its discretion in choosing to reject APHIS's proposed mitigation measures in favor of a broader injunction to prevent more irreparable harm from occurring.

The district court applied the traditional balancing test, and not a categorical rule, in fashioning the injunction here, *see eBay*, 547 U.S. at 394, 126 S.Ct. 1837, and its factual conclusions were not clearly erroneous. The district court therefore did not abuse its discretion in formulating the remedy.

Lack of an Evidentiary Hearing

Monsanto and Forage Genetics also argue that the district court erred in declining to hold an evidentiary hearing before entering the permanent injunction. The district court had already held a hearing on whether an EIS was required, and heard testimony during a March hearing from Forage Genetics' president on the scope of preliminary injunctive relief.

Monsanto and Forage Genetics requested that the district court hold an evidentiary hearing before issuing the permanent injunction so that the district court could, as described by that court, "assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." This evidence concerned the degree of the risk of environmental damage. There were voluminous documentary submissions from both sides disputing, among other things, the likelihood of genetic

contamination of non-Roundup Ready alfalfa fields. APHIS did not request an evidentiary hearing.

The district court reviewed the documentary submissions, but it declined to hold a further hearing. It explained that holding the type of evidentiary hearing suggested by the intervenors "would require this Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS; defendants are in effect asking this Court to accept its truncated EIS without the benefit of the development of all the relevant data and, importantly, without the opportunity for and consideration of public comment." The court cited *Idaho Watersheds* in concluding that it did not need to conduct an extensive inquiry, involving scientific determinations, to determine what interim measures are necessary to protect the environment "while the [government] conducts studies in order to make the very same scientific determinations." 307 F.3d at 831.

Monsanto and Forage Genetics are correct that generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed. *See United States v. Microsoft Corp.*, 253 F.3d 34, 101-03 (D.C.Cir.2001); *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir.1988). The district court did not believe defendants had established any material issues of fact that were in dispute in the case before the court. Rather, it viewed the disputed matters to be issues more properly addressed by the agency in the preparation of an EIS.

The injunction at issue here, as in *Idaho Watersheds*, is not a typical permanent injunction, which is of indefinite duration. A permanent injunction

to ensure compliance with NEPA has a more limited purpose and duration. Thus, in *Idaho Watersheds*, a case involving a NEPA violation, this court held that an evidentiary hearing was not required before issuing an injunction. *See* 307 F.3d at 831. We distinguished this context from *Microsoft*, and the "normal injunctive setting," principally because *Idaho Watersheds* involved interim measures that would be in place only until the EIS was completed, at which point the parties would have "extensive input" into the determination of which measures would be adopted permanently. *Id.* at 831; accord *Mont. Wilderness Ass'n v. Fry*, 310 F.Supp.2d 1127, 1155-56 (D.Mont.2004) (holding that, under *Idaho Watersheds*, an evidentiary hearing was not required before imposing interim injunctive relief). The district court there had sought to avoid the catch-22 situation where an evidentiary hearing would require it to perform the same type of extensive inquiry into environmental effects that the ordered EIS will require the government agency to perform. *Idaho Watersheds*, 307 F.3d at 831. We agreed with the district court's approach, holding that an evidentiary hearing was not required because the measures were "interim measures designed to allow for a process to take place which will determine permanent measures, and all parties will have adequate opportunity to participate in the determination of permanent measures (and if need be challenge the outcome in court)." *Id.* We observed that requiring a hearing would duplicate the BLM's efforts and divert its resources from those efforts. *Id.* The district court here correctly denied a hearing because the same situation is presented in this case.

Monsanto and Forage Genetics also contend that even if *Idaho Watersheds* authorizes entry of a permanent injunction without an evidentiary hearing, it does so only if the court adopts the agency's recommendation. We explained in *Idaho Watersheds*, however, that the key reason a further evidentiary hearing was not required was that the injunction would be in place only until the necessary environmental studies were conducted. *Id.* In this case, as in *Idaho Watersheds*, the government does not contend that a further hearing is required, perhaps in order to avoid the duplication of resources we described in *Idaho Watersheds*. The dissent insists on remanding for a hearing that the government has never contended would be appropriate in this case.

The district court here considered extensive evidentiary submissions from all parties pertaining specifically to the remedy phase, as it was required to do. *See Microsoft*, 253 F.3d at 103 (holding that district court had erred in failing to consider the remedies-phase evidentiary submissions of defendant). It held two hearings during the remedies phase, one of which included testimony from the president of Forage Genetics on the scope of preliminary injunctive relief. It then determined that it should not conduct a hearing that would duplicate APHIS's efforts in preparing the EIS ordered by the court.

The injunction involved only interim measures pending APHIS's compliance with NEPA, and the district court considered extensive remedies-phase evidence. The court did not err in declining to hold a further hearing before entering the injunction pending the agency's completion of environmental study the law

undisputedly required it to perform before approving this product for unrestricted use.

The district court's order is **AFFIRMED**.

N. RANDY SMITH, Circuit Judge, dissenting:

The district court's failure to conduct the requisite evidentiary hearing prevents me from joining the majority's opinion. The majority correctly recognizes that the district court was required to conduct an evidentiary hearing before issuing a permanent injunction under Federal Rule of Civil Procedure 65 unless (1) the facts were undisputed; or (2) the adverse party expressly waived its right to an evidentiary hearing. *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir.1988). Despite recognizing this clear precedent, the majority affirms the district court's decision to proceed without the requisite evidentiary hearing, and, in so doing, creates an altogether new exception to the evidentiary hearing requirement we recognized in *Charlton*.

The majority acknowledges that the facts were sharply disputed by the parties. To be sure, the parties disputed almost every element of the facts underlying the proposed injunction. Specifically, the parties disputed the risk of genetic contamination that could occur if the district court did not enjoin the further planting of Roundup Ready alfalfa while APHIS prepared the EIS. Given that the parties disputed the facts underlying the need for, and scope of, any injunctive relief, the first recognized exception to the evidentiary hearing requirement was unavailable. *See Charlton*, 841 F.2d at 989.

The second recognized exception was unavailable too. As the district court noted, Monsanto and Forage

Genetics requested an evidentiary hearing "apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." In discussing Monsanto's and Forage Genetics' request for an evidentiary hearing, the majority notes APHIS's failure to request an evidentiary hearing. This failure, however, is insignificant given that Monsanto and Forage Genetics already had made their request. Because the parties did not consent to proceed without an evidentiary hearing, the other recognized exception to the evidentiary hearing requirement was unavailable. *See id.* Given those facts, we should reverse to allow the district court to conduct an evidentiary hearing. But that is not what the majority does here.

The majority instead relies on *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 823 (9th Cir.2002), to create an altogether new exception to the evidentiary hearing requirement. The majority reasons that, because the injunction will only last as long as it takes APHIS to conduct an EIS, this is not a typical permanent injunction requiring typical procedural safeguards. The majority next assumes that an evidentiary hearing would result in waste of agency resources because the hearing would require consideration of the same issues that APHIS must resolve in conjunction with the EIS.

As the majority correctly recognizes, we affirmed the district court's refusal to conduct an evidentiary hearing in *Idaho Watersheds* in light of the temporary nature of the injunction. But this case isn't *Idaho Watersheds*. There, the district court deferred to the

agency's recommendations and expertise—thereby resulting in an efficient resolution pending completion of the agency determinations. Conversely, in this case, the district court expressly rejected APHIS's proposed injunction and independently fashioned a permanent injunction without the benefit of live testimony subject to the adversarial process. These shortcomings resulted in a critical failure by the district court and deprived the parties of important procedural rights when it came to shaping the scope of any potential injunction.

The majority argues that the district court didn't need to conduct an evidentiary hearing because it held two hearings during the remedies phase of proceedings and had the benefit of live testimony from Forage Genetics' president Mark McCaslin. With due respect to both counsel and Mr. McCaslin, this falls far short of the standards we have articulated for a hearing prior to issuing an injunction. The hearings cited by the majority were simply arguments by counsel construing the written submissions and documentary evidence. Although helpful, argument by counsel is no substitute for live testimony when it comes to determining the nature and extent of the alleged injury, where the balance of hardship lies, and the scope of the injunction. Based on this record, it appears that the district court allowed Mr. McCaslin to speak without notice to the parties or opportunity for cross examination. Given that circumstance, Mr. McCaslin's testimony was little better than no testimony.

The district court could have used the evidentiary hearing to better ascertain the nature of the alleged injury and to further understand the balance of the hardships associated with the parties' varying

proposals for injunctive relief. It didn't. The district court also could have used the hearing to test the merits of the parties' positions. An evidentiary hearing would have allowed for cross examination of the witnesses on their written testimony and submissions. Instead the district court rejected the agency's proposal and fashioned its own permanent injunction based on argument of counsel, the written record, and ad hoc testimony from Mr. McCaslin. These shortcomings were significant because the district court might have reached a different result had it held an evidentiary hearing before reaching a decision.

The evidentiary hearing requirement is essential because it allows the district court an opportunity to consider the witnesses' credibility in the face of cross examination. That step is what justifies the abuse of discretion standard of review under which we consider a district court's decision to grant or deny injunctive relief. If a district court skips the requisite evidentiary hearing, we have exactly the same record on appeal as the district court did below. In that circumstance, I see no reason to afford the district court any discretion when reviewing its decision to grant or deny an injunction. For that reason, I consider it to be an abuse of discretion for a district court not to hold an evidentiary hearing unless the case fits in either of the recognized *Charlton* exceptions or the district court accepts the agency's proposal for temporary injunctive relief, as occurred in *Idaho Watersheds*.

Based on this record, I have serious concerns about the scope of the injunction entered by the district court. At best, the record reflects sparse evidence of hay-to-hay gene transmission of RRA alfalfa in some areas of the country under certain planting conditions.

Further, I see no good evidence of hay-to-seed or seed-to-seed gene transmission. Yet the district court entered a nationwide injunction on the planting of Roundup Ready alfalfa while APHIS completes an EIS. This nationwide injunction has severe economic consequences for Monsanto, Forage Genetics, and for the farmers and distributors who planned on RRA alfalfa being available. I would be more comfortable with a nationwide injunction had the district court held an evidentiary hearing to consider live testimony, listened to cross examination, and resolved any credibility issues between the witnesses. But no such hearing occurred and I therefore have no confidence in the need for a nationwide injunction pending completion of the EIS.

By affirming the district court's refusal to conduct an evidentiary hearing, the majority has created a third exception to the evidentiary hearing requirement. Under this decision, a district court now can forego conducting an evidentiary hearing simply because (1) the injunction may dissolve at some point and (2) the issues, to be raised at the hearing, overlap with the issues the agency must consider. Instead of giving deference to the agency's expertise, *see The Lands Council v. McNair*, 537 F.3d 981, 988, 992-93, 2008 WL 2640001, *4, *8-9 (9th Cir.2008) (en banc), the majority gives deference to the district court despite its wholesale rejection of the agency's proposal and its failure to hold an evidentiary hearing. There aren't many environmental cases that don't fit into the majority's newly-created exception. This is a mistake, as it would eliminate a "significant procedural step[,]" *Charlton*, 841 F.2d at 989, without any real justification. I would instead remand so that the

district court could conduct an evidentiary hearing on the merits and scope of the permanent injunction.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEERTSON SEED FARMS, an Oregon business; Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp.,

v.

Mike JOHANNS, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants.

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors,

and

Monsanto Company, Defendant-Intervenor-Appellant.

Geertson Seed Farms, an Oregon business; Trask Family Seeds, a South Dakato business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.;

Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp., Plaintiffs-Appellees,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture, Defendants,

Monsanto Company, Defendant-Intervenor,

and

Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors-Appellants.

Trask Family Seeds, a South Dakota business; Center for Food Safety, a Washington DC nonprofit corp.; Beyond Pesticides, a Washington DC nonprofit corp.; Cornucopia Institute, a Wisconsin nonprofit corp.; Dakota Resource Council, a North Dakota nonprofit corp.; National Family Farm Coalition, a Michigan nonprofit corp.; Sierra Club, a California nonprofit corp.; Western Organization of Resource Councils, a Montana nonprofit corp.; Geertson Seed Farms, an Oregon business, Plaintiffs-Appellees,

and

Geertson Seed Farms, an Oregon Corp., Plaintiff,

v.

Mike Johanns, in his official capacity as Secretary of the U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture; Steve Johnson, in his official capacity as Administrator of the United States Environmental Protection Agency, Defendants-Appellants

and

Monsanto Company; Forage Genetics, Inc.; John Grover; Daniel Maderos; Mark Watte, Defendant-Intervenors.

NOS. 07-16458, 07-16492, 07-16725.

Argued and Submitted June 10, 2008.
Filed June 24, 2009.

570 F.3d 1130

Before: MARY M. SCHROEDER and N. RANDY SMITH, Circuit Judges, and VALERIE FAIRBANK,* District Judge.

Opinion by Judge SCHROEDER; Dissent for Judge N. SMITH.

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* The Honorable Valerie Fairbank, United States District Judge for the Central District of California, sitting by designation.

ORDER AND AMENDED OPINION

ORDER

The opinion and dissent filed September 2, 2008, and appearing at 541 F.3d 938 (9th Cir.2008), are hereby amended. The amended opinion and dissent are filed concurrently with this Order.

With these amendments, Judges Schroeder and Fairbank have voted to deny the petition for panel rehearing and recommend denial of the petition for rehearing en banc. Judge N.R. Smith votes to grant the petition for panel rehearing and rehearing en banc.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for panel rehearing and rehearing en banc is **DENIED**. No further petitions for rehearing will be accepted.

[Amended Opinion Reproduced at Pet. App. 1a-26a]

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON FARMS INC. et al.,
Plaintiffs,
v.
MIKE JOHANNS, et al.,
Defendants, and
MONSANTO COMPANY, et al.,
Intervenor-Defendants. /

No. C-06-01075 CRB

JUDGMENT

The Court having granted plaintiffs' motion for summary judgment on their NEPA claims by Memorandum and Order dated February 13, 2007, and having dismissed plaintiffs' remaining claims, judgment is entered in favor of plaintiffs and against the federal defendants on the NEPA claims.

The federal defendants' June 14, 2005 Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate is VACATED. Before granting Monsanto's deregulation petition, even in part, the federal defendants shall prepare an environmental impact statement ("EIS"). Until the federal defendants prepare the EIS and decide the deregulation petition, no Roundup Ready alfalfa, known as J101 and J163, may be planted. This injunction does not apply to the permit process for regulated articles administered by the Animal and Plant Health Inspection Service ("APHIS").

Roundup Ready alfalfa planted before March 30, 2007 may be grown, harvested and sold subject to the following conditions. In particular, within 45 days of this Judgment, the federal defendants shall issue an administrative order imposing the following requirements:

I. Pollinators shall not be added to Roundup Ready alfalfa fields grown only for hay production.

II. Farm equipment used in Roundup Ready alfalfa production shall be properly cleaned after use.

   A. Cleaning procedures for harvesters, tractors and tillage equipment shall be submitted to and approved by APHIS prior to implementation.

   B. Cleaning procedures shall be designed to minimize the risk of Roundup Ready alfalfa seed and hay movement from authorized production sites

   C. All equipment shall be cleaned in accordance with the approved procedures before it leaves the farm on which in came in contact with Roundup Ready alfalfa.

III. Roundup Ready alfalfa shall be handled and clearly identified to minimize commingling after harvest. Immediately after harvest, growers or seed producers shall store Roundup Ready alfalfa in specifically designated and clearly labeled containers.

Monsanto, Forage Genetics and APHIS shall work together to ensure that all Roundup Ready alfalfa farmers are aware of the above requirements.

Within 30 days of the judgment, Forage Genetics shall provide APHIS with GPS or plat mats identifying the location of all Roundup Ready alfalfa seed production acreage as well as the field size and GPS locations of Roundup Ready alfalfa hay fields for the 17 Western states in which Forage Genetics collects such information. APHIS shall make such information publicly available as soon as practicable, including, but not limited to, making such information available on the appropriate government website. Forage Genetics shall also use its best efforts to obtain field size and GPS locations of Roundup Ready alfalfa in the remaining states and provide such information to APHIS for public disclosure.

The parties shall jointly submit a written status report within 60 days of the date of this Judgment to update the Court on defendants' compliance with the injunction.

IT IS SO ORDERED.

Dated: May 3, 2007

/s/ Charles R. Breyer
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS INC., et al., Plaintiffs,	)	Case No. C-06-1075 (CRB) (EDL)
vs.	)	**AMENDED**
MIKE JOHANNS, et al., Defendants,	)	**JUDGMENT**

On May 3, 2007, this Court issued its Judgment. Thereafter, the Court granted defendants' Rule 59 Motion to Alter or Amend 3 May 2007 Judgment. Order Re: Motion to Amend Judgment (filed 26 June 2007)("Rule 59 Order"). Pursuant to the Rule 59 Order, the Court's Judgment is hereby amended, as follows.

I. Storing Roundup Ready Alfalfa in Clearly-Labeled Containers

In Section III of the Judgment, the Court required APHIS to impose certain handling, identification, and containment standards for Roundup Ready Alfalfa ("RRA") in an administrative order.

These standards shall not be applied to RRA hay, unless that hay leaves its farm of origin. Where RRA hay leaves its farm of origin, it need not be containerized but instead shall be clearly labeled.

II. Cleaning Procedures

In Section II, Subsection A of the Judgment, the Court required APHIS to issue an administrative order enabling it to both impose and individually

approve certain cleaning procedures "prior to implementation."

In lieu of this requirement that APHIS approve individual cleaning procedures before implementation, APHIS shall publish and distribute a best practices guide for the cleaning of equipment used to produce RRA hay and seed. This guide shall be available on the APHIS website by July 13, 2007, and APHIS shall also begin distributing it by mail at that time to RRA hay and seed producers.

III. Deadline for Providing RRA Field Information to the Government

The Judgment also required Monsanto and Forage Genetics to provide APHIS with the RRA field location information described therein. On or before August 27, 2007, Monsanto and Forage Genetics shall file a status report describing their progress in supplying the remaining RRA hay crop location information (1) specific to the 17 Western states and (2) specific to the eastern United States.

IV. Public Disclosure of the Location of RRA

In its Judgment, the Court required APHIS to disclose RRA location information on its website "as soon as practicable." Pursuant to the Court's Rule 59 Order, APHIS will disclose the RRA locations to farmers only, under a three-part disclosure mechanism.

First, within one week after entry of this Court's Amended Judgment, APHIS shall disclose to farmers the counties in the 17 Western states in which RRA seed or hay fields are located. This disclosure shall be on the website of APHIS' Biotechnology Regulatory Service (APHIS/BRS) homepage. It shall be accessed by a link at this website's bottom right side that reads "I want to learn about the status of Roundup Ready

alfalfa." Further, on the same website, and within 30 days of the status report filed by Monsanto and Forage Genetics, described above, APHIS shall publish a time line for the expected disclosure of RRA location information for the remaining Eastern states.

Second, within two weeks after entry of the Court's Amended Judgment, APHIS shall specify both on this website and in a the Federal Register a toll-free number that farmers in or adjacent to those identified counties may use to request the distances from the nearest RRA fields to their crops. Upon calling this number, a farmer shall certify to APHIS that the caller is a farmer that either grows alfalfa now or intends to grow alfalfa at an existing location in or adjacent to a county identified on the APHIS website.

Third, APHIS will respond as quickly as practicable to requests from farmers through the toll free number, either immediately or by the next working day whenever feasible, and will use its best efforts when questions arise regarding imprecise data or under other unanticipated circumstances to respond within three working days. In responding to a request by a farmer hereunder, APHIS will provide the requesting farmer with the distances, within the county or adjacent county identified, from the nearest RRA fields to the requestor's crop location(s). APHIS shall provide such distances for five such RRA fields if five or more of such fields exist in the relevant county or adjacent county.

V. APHIS Administrative Order

APHIS shall implement the Court's Judgment, as amended, by issuing an administrative order on or before July 13, 2007. It shall be posted on the APHIS website.

Dated: July 23, 2007

CHARLES R. BREYER
United States District Judge
UNITED STATES DISTRICT COURT

IT IS SO ORDERED
s/Judge Charles R. Breyer
Judge Charles R. Breyer
NORTHERN DISTRICT OF CALIFORNIA

CONSTITUTION OF THE UNITED STATES

Amendment V

No person shall ... be deprived of life, liberty, or property, without due process of law ....

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 55. NATIONAL ENVIRONMENTAL POLICY SUBCHAPTER I. POLICIES AND GOALS

42 U.S.C. § 4332

§ 4332. Cooperation of agencies; reports; availability of information; recommendations; international and national coordination of efforts

The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall—

* * *

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

(i) the environmental impact of the proposed action,

(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,

(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section 552 of title 5, and shall accompany the proposal through the existing agency review processes;

* * *

TITLE 40. PROTECTION OF ENVIRONMENT
CHAPTER V. COUNCIL ON ENVIRONMENTAL QUALITY
PART 1508. TERMINOLOGY AND INDEX

40 C.F.R. § 1508.9

§ 1508.9 Environmental assessment.

Environmental Assessment:

(a) Means a concise public document for which a Federal agency is responsible that serves to:

(1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact.

(2) Aid an agency's compliance with the Act when no environmental impact statement is necessary.

(3) Facilitate preparation of a statement when one is necessary.

* * *

TITLE 40. PROTECTION OF ENVIRONMENT
CHAPTER V. COUNCIL ON ENVIRONMENTAL QUALITY
PART 1508. TERMINOLOGY AND INDEX

40 C.F.R. § 1508.13

§ 1508.13 Finding of no significant impact.

Finding of no significant impact means a document by a Federal agency briefly presenting the reasons why an action, not otherwise excluded (§ 1508.4), will not have a significant effect on the human environment and for which an environmental impact statement therefore will not be prepared. It shall include the environmental assessment or a summary of it and shall note any other environmental documents related to it (§ 1501.7(a)(5)). If the assessment is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	NO. C-06-01075 CRB **DECLARATION OF ERIK FREESE**

I, Erik Freese, declare:

1. I operate a 4,000-acre farm in Dixon, California. I grow corn, sunflowers, beans, wheat, grass seed and alfalfa for forage. I have been farming for eleven years. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. We currently have 1,500 acres planted with alfalfa. In the fall of 2005 we planted 50 acres of RoundUp Ready Alfalfa ("RRA,") and 400 more acres in the fall of 2006. The balance is planted with conventional alfalfa. My current plan is to replace my conventional alfalfa fields with RRA after those fields have run their course.

3. The results from our first 50 acres of RRA have been great. Our RRA stands have yielded higher tonnage and quality alfalfa than our conventional alfalfa stands. As a result, in our first cutting alone we were able to receive $40-45 more per ton than for our conventional alfalfa based on weed-tee alfalfa. This also allows us to establish a "brand name" to customers which entices them to keep buying the "Freese Weed-Free Alfalfa."

4. I am also hopeful that using RRA will result in longer lasting stands. A typical alfalfa stand lasts anywhere from four to six years depending on the weather and the field type. I hope to get at least seven years out of the RRA stands. I believe this is possible because RRA allows you to start with a clean field. The best way to have a healthy stand is to start with a clean field. The best way to control weeds is to have a healthy stand, which is more likely if you start with a clean field. If the alfalfa is allowed to grow from the beginning without interference from weeds, the alfalfa gets established which in turn prevents weeds from ever taking hold. This in turn should result in a longer lasting stand.

5. From a cost standpoint alfalfa cultivation is very front loaded, with ground preparation costs, seed costs and herbicide costs all occurring at the beginning of the stand. For the first two years you recover your costs, but you don't start making money until year three. Obviously, a longer lasting stand with RRA will result in a greater return on investment.

6. RRA is also a lot easier to use. With RRA, you simply apply one application of RoundUp to the field at the beginning of the stand and the rest takes care of

itself. Cultivating conventional alfalfa, by contrast, is more complicated. With conventional alfalfa, multiple applications of different chemicals must be used. The results achieved from the use of these chemicals can be affected by the weather. If things don't go just right at the beginning of a conventional alfalfa stand, the quality is affected for the remaining life of the stand. The alternatives to RoundUp are also more expensive. With conventional alfalfa herbicide costs are approximately $125 per acre per year. RRA, on the other hand, may require one or two applications of RoundUp per year at a cost of $10 to $30 per acre. This results in a substantial savings. For example, last year I only had to apply one application of RoundUp to my RRA fields.

7. Another benefit of RRA is that RoundUp is one of the safest chemicals out there: it dissipates rapidly in the soil, there is no residual, in fact it is so safe it is available at hardware stores and can be used without special equipment. The herbicides that must be used on conventional alfalfa, such as Velpar or Gramoxone, are much more toxic. For example, when we use Velpar, we must file a notice of Intent with the county 24 hours in advance, the county must inspect the site to make sure that we will not be spraying in an area which could result in water contamination or drift into residential areas, and my crews have to wear special equipment (respirators, protective clothing and the like).

8. When I purchased RRA I was required to sign the Monsanto Technology/Stewardship Agreement, which requires that I follow the practices set forth in the Technology Use Guide ("TUG"). One of the requirements of the TUG is that RRA be harvested at

or before 10% bloom. This isn't a problem for us as it is well known that at or before 10% bloom is when the harvest is most valuable and if I want to get the greatest price for my hay, I need to harvest at that time.

9. If I could not use RRA or was required to plow under my RRA fields, it would have a hugely negative impact on my operation. Given that I am at the beginning of the cycle of my RRA stands and have not yet recovered my costs, such an order at this time would be the worst thing that could occur. I estimate that I would suffer losses in the amount of $1,000/acre under such a scenario.

I declare under penalty of perjury under the laws of the State of California and the United States of America, that the foregoing is true and correct. Executed this 28th day of February 2007 at Dixon, California.

/s/ Erik Freese 2/28/07

ERIK FREESE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, Inc., *et al.*, Plaintiffs, v. MIKE JOHANNS, *et al.*, Defendants, and MONSANTO COMPANY, Proposed Intervenor-Defendant.	Case No. C 06-1075 CRB **DECLARATION OF PAULETTE PIERSON, IN SUPPORT OF MONSANTO COMPANY'S MOTION TO INTERVENE** Date: April 6, 2007 Time: 10:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

DECLARATION OF PAULETTE PIERSON, IN SUPPORT OF MONSANTO COMPANY'S MOTION TO INTERVENE

I, Paulette Pierson, declare as follows:

1. I am the Technology Development Manager for Roundup Ready®[1] Alfalfa and Roundup Ready Sugarbeet for the Monsanto Company ("Monsanto"), a

[1] ®Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

position I have held since 2005. Monsanto is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality.

2. In my capacity as Technology Development Manager for Roundup Ready Alfalfa, I am responsible for overseeing the technical aspects of the development and commercialization of this product. My responsibilities in connection with Roundup Ready alfalfa have included overseeing the technical aspects of the full commercial launch of Roundup Ready alfalfa in February 2006; developing technical recommendations for the use of Roundup Ready alfalfa and for weed resistance management strategies; and providing technical and strategic direction for commercialization of Roundup Ready alfalfa in Canada, Mexico, and Argentina.

3. I was raised on a dairy farm in Minnesota, and my family has been in dairy farming for four generations. I am an agronomist by training and have a Bachelor of Science degree in agronomy from the University of Minnesota (1978), a Masters of Science in agronomy from the University of Kentucky (1982), and a Ph.D. in agronomy from The Ohio State University (1994). My doctoral dissertation focused on alfalfa breeding.

4. I first joined Monsanto in 1982, serving first as a Research Biologist II and then as a Senior Research Biologist until 1986. From 1986 to 1998, I worked at The Ohio State University, first as a Research Associate/Tissue Culture Specialist focusing on plant pathology, then as a Graduate Research and Teaching

Assistant in agronomy, and finally as a Post-doctoral Researcher in plant pathology.

5. I returned to Monsanto in 1998, and since then have held several positions of increasing responsibility including: Manager of Agronomic Training for DEKALB Genetics (a Monsanto subsidiary) (1998-1999); Technical Information Specialist (1999-2002); Technology Development Manager for Monsanto's Central Ohio sales team (2002-2003); Product Labels Manager (2003-2005); and my current position with the company. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

6. I have personal knowledge of the matters referred to herein and if called upon to testify could and would testify truthfully thereto.

Background On Alfalfa

7. Alfalfa is a legume grown almost exclusively for animal feed (forage) and harvested primarily in the form of hay. It is a perennial crop, usually grown for three to five years before it is plowed under and a rotation crop is planted for one or more years. During its lifespan, within each growing season, alfalfa is cut (mown) and harvested at regular intervals. Approximately once per month, it is baled for hay, green chopped, or pastured. Alfalfa is highly valued as livestock feed, providing more nutrition and better digestibility than other feeds.

8. The presence of weed seeds and weed biomass in forage lowers the on-farm or cash market value of the hay and negatively impacts the nutritive value to the livestock fed the hay. Weeds are a major problem in alfalfa, particularly in the alfalfa plants' first year of growth (the seeding year), when the frail alfalfa

seedlings are easily out-competed for water, nutrients and space by stronger, faster growing weeds. In the later years of the alfalfa field (or stand), weeds can overtake older, weaker alfalfa plants, thereby, lowering the quality and value of hay and forcing earlier termination (plow-down) of the stand.

9. Roundup Ready alfalfa provides an important new tool in combating weeds in alfalfa production. Roundup branded agricultural herbicides (the active ingredient of which is glyphosate) control more than 100 species of grassy and broadleaf weeds, so they can remove nearly every species that appears during the alfalfa field lifespan. Roundup Ready alfalfa is engineered to be tolerant to glyphosate, so glyphosate is safe for use on Roundup Ready alfalfa during that critical first year, when the alfalfa is delicate and the weeds are most aggressive. Giving the young alfalfa a good start promotes a full, strong crop of alfalfa in the field in later years, minimizing bare spots in the field where weeds could later take root. This strong crop results in high yield and high quality hay throughout the multi-year stand life, meaning better nutrition for livestock and higher economic value for the grower.

Stewardship Practices And Biological Barriers To Gene Transmission From Roundup Ready Alfalfa Forage

10. Transmission of genetic traits from Roundup Ready alfalfa grown for forage is extremely unlikely both for fundamental biological and economic reasons and because Monsanto requires specific stewardship practices by contract.

Alfalfa Cultivation and Biology

11. Alfalfa forage growers have a strong incentive to cut at the pre-bud to early (10%) bloom stage because feed quality and market value drops rapidly after the onset of bloom. Forage quality is critical to dairy cow productivity. Producers who manage alfalfa forage fields for the dairy market (the primary customers for Roundup Ready alfalfa) cut their hay prior to flower development, in order to optimize forage value per ton.

12. Cutting alfalfa at the pre-bud to early (10%) bloom stage is always preferable to cutting late for best forage quality. Forage growers watch the weather and will cut early rather than risk a hay stand going beyond 10% bloom as a result of weather delays, because that delay rapidly and dramatically reduces the nutritional value of the forage. Delaying cutting due to weather also delays subsequent cuttings and puts at risk the yield potential of the stand for the season. Weather-related concerns, therefore, are unlikely to cause forage growers to delay cutting beyond the 10% bloom stage.

13. In addition, Roundup Ready alfalfa forage growers have a further incentive to harvest their crop in a timely fashion, because they pay a premium for their Roundup Ready alfalfa seed above what they would pay for conventional alfalfa seed. To make this investment worthwhile, it is in Roundup Ready alfalfa forage growers' commercial interests to manage their crop to maximize its value—including mowing it promptly, before flowering occurs and hay value drops.

14. Roundup Ready alfalfa plants must flower before they can produce pollen. Cross-pollination is the

only possible mechanism for transfer of genetic material from Roundup Ready alfalfa plants to other alfalfa plants. Because Roundup Ready alfalfa produced for forage is harvested before flowering, it is highly unlikely that such pollination will occur.

15. Even if some limited flowering occurs, the potential for pollen and gene flow between forage fields is extremely low because (i) pollination would require the two fields to flower at the same time; (ii) alfalfa requires an insect pollinator (usually leafcutter bees or honeybees) for pollination; (iii) alfalfa pollinators are not attracted to forage alfalfa fields; and (iv) alfalfa does not shed pollen to the wind. Production of alfalfa seed generally requires seed growers to stock bees on seed production fields. Bees are not stocked on forage production fields since they are not needed for forage production. Thus, unless a grower were to stock bees on a forage production field and intentionally leave that field uncut so as to permit flowering, and unless flowering in that field and a neighboring field actually occurred at the same time, cross-pollination between the fields would be extremely unlikely.

16. In regions where leafcutter bees are not prevalent, the likelihood of pollination is even lower because honeybees, even if present, mainly collect nectar, not pollen, and are therefore much less likely to cause pollination.[2] Studies have shown that only one honeybee in 100 collects pollen from alfalfa,[3] that only

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[2] Crane, J.H. 2002. Pollinating bees (*Hymenopters: Apiformes*) of U.S. alfalfa compared for rates of pod and seed set. J. Econ. Entomol. 95(1): 22-27.

[3] Root, A.I. 1983. The ABC and XYZ of Bee Culture 6-7.

one in five of their floral visits results in pollination,[4] and that honeybees tend to avoid alfalfa if other crop or weed flowers are present.[5]

17. In the highly unlike event that genetic material from Roundup Ready alfalfa were transferred through pollination to a non-Roundup Ready alfalfa forage field, the frequent cutting of alfalfa makes it highly unlikely that the pollinated plant would be allowed to grow long enough to produce a mature seed. But even if such a seed were permitted to mature, it is highly unlikely that it would germinate. Alfalfa seeds are not light enough to be transported by wind. Seeds that fall close to the existing "parent" stand are unlikely to survive because of "autotoxicity," a phenomenon resulting from the release by established alfalfa plants of natural toxins that prevent the germination or survival of seeds. Even if seeds were somehow transported away from the existing alfalfa stand, germination and survival is unlikely because of the growing conditions required: alfalfa seed requires seed to soil contact and adequate moisture to survive, and seedlings are easily outcompeted by established vegetation.

18. These factors together make the likelihood of gene transmission from Roundup Ready alfalfa forage fields to other fields infinitesimally small. For example, a 2006 peer-reviewed publication from the University of California, attached hereto as Exhibit B, found that, although gene transfer from one hay field to another is theoretically possible, the range of

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[4] Crane, *supra*.

[5] Teuber, L.R., et al. 2005. Gene flow in alfalfa (*Medicago sativa L.*) when honeybees (*Apis mellifera*) are used as pollinators. 2005 North Central Weed Science Society Proceedings.

environmental barriers make gene movement very unlikely and the likelihood that a trait such as glyphosate tolerance would show up where it was not intended infinitely small (*i.e.*, far less than 0.001% of field biomass).

Cultivation Practices and Monsanto's Technology/Stewardship Agreement

19. Any possibility of gene transmission from Roundup Ready alfalfa to other alfalfa is reduced yet further by the stewardship practices contractually required by Monsanto.

20. Each forage grower who purchases Roundup Ready alfalfa, or any other Roundup Ready crop product, must enter into a limited use license with Monsanto and must sign and comply with the 2007 Monsanto Technology/Stewardship Agreement ("MTA"), which is attached hereto as Exhibit C. The MTA incorporates by reference and requires the grower to follow Monsanto's Technology Use Guide ("TUG"), which sets forth requirements and best practices for the cultivation of Roundup Ready alfalfa, among other Monsanto products. The portion of the 2007 TUG relating to Roundup Ready alfalfa is attached hereto as Exhibit D.

21. The portions of the MTA and TUG that apply to all Roundup Ready alfalfa forage growers, among other things, (i) limit use of Roundup Ready alfalfa seed solely to produce forage for feed uses, (ii) provide for timely cutting of the alfalfa to prevent alfalfa seed development, and (iii) restrict sale of the forage produced only to those countries, such as Japan, where regulatory approvals have been granted. In certain geographic areas, such as the Imperial Valley of

California, additional use limitation agreements are required. Monsanto checks compliance with license requirements to ensure that no unauthorized activities (including seed production) are occurring. In addition, forage growers in the western states, where alfalfa seed is grown, must provide Global Positioning System ("GPS") coordinates for use by Monsanto to facilitate compliance audits of those forage producers. All Roundup Ready alfalfa seed is packaged with a unique purple seed coating and "Roundup Ready Alfalfa" seed-bag labeling.

22. Under the TUG, forage Roundup Ready alfalfa crops are intentionally managed to prevent pollen and seed formation. Among other things, the TUG requires Roundup Ready alfalfa forage growers to harvest their crop at the pre-bud to early (10%) bloom stage in geographies where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions are such that forage alfalfa is otherwise allowed to stand and flower late in the season.

* * *

Importance of Roundup Ready Alfalfa to Agriculture and the Environment

27. Roundup Ready alfalfa, the first commercial perennial crop with Roundup Ready technology, offers an effective, environmentally responsible alternative weed control system in alfalfa that contributes significantly to grower profits and the production of enhanced quality animal feed for the dairy industry.

28. Roundup Ready alfalfa was first commercially introduced on a limited, managed basis in 2005, and was fully launched in 2006 after Japan approved its use for

feed. Over 200,000 acres have been planted with Roundup Ready alfalfa to date. Monsanto estimates that the value of the Roundup Ready alfalfa stands already planted to date to farmers across the United States is over $450 million, based on expected yields, a typical stand life of five years, and current prices for high quality hay of around $140 per ton.

29. Roundup Ready alfalfa provides a wide range of benefits to farmers and downstream users. Use of Roundup Ready alfalfa enables growers to greatly improve weed management, increase yields, produce a better quality crop, be more profitable, and plan crop rotations so they can efficiently manage their land use. In addition, the higher quality hay produced from Roundup Ready alfalfa enables dairies to produce more milk per ton of alfalfa forage.

30. The Roundup Ready alfalfa weed control system simplifies and improves weed management during stand establishment, enhances the flexibility of weed control in established stands, improves forage quality by reducing the weed content of harvested forage, and increases income for farmers. Weeds consistently reduce the yield of pure alfalfa harvested and negatively affect forage nutritional quality. Weed control is especially critical and challenging during stand establishment and the presence of weeds in mature fields can diminish the quality of the hay, reduce its value as feed and cause producers to sustain financial penalties commensurate with a lesser grade hay.

31. Roundup branded agricultural herbicides (glyphosate) are broad spectrum herbicides that control more than 100 species of grassy and broadleaf

weeds, so they can remove nearly every species that appears during the alfalfa field lifespan. Because glyphosate does not persist in soil, farmers can manage crop rotation programs without concern that residual glyphosate will injure the next crop to be planted after it is used, or about label restrictions against replanting after use that are designed to avoid such injury. In addition, the superior crop safety of the Roundup Ready alfalfa system compared to other herbicides used in alfalfa increases the likelihood that a newly established stand will mature into a pure stand, with higher nutrient and economic value. For example, one recent study with which I am familiar estimates that, in California alone, the value of alfalfa hay is reduced by $21 million per year because of weeds in harvested hay. The same study estimates that Roundup Ready alfalfa would increase farmers' net income by $17.6 million per year in California alone. (See L.P. Gianessi, *et al.*, Plant biotechnology: Current and potential impact for improving pest management in U.S. agriculture – An analysis of 40 case studies (2002), available at http://www.ncfap.org.)

32. The Roundup Ready alfalfa weed control system provides distinct advantages over non-glyphosate based weed control systems. Research shows that if effective herbicides are not used during the establishment phase of alfalfa, weeds can represent up to three quarters of the first cutting. But several currently available herbicides labeled for use in seedling alfalfa can cause crop injury, which impairs seedlings' ability to compete with weeds. Poorly established stands never fully recover. In addition, many of the non-glyphosate herbicides used in alfalfa have a narrow window of application or do not

individually control the full spectrum of weeds infesting alfalfa fields. And due to label restrictions, growers can be forced to delay the first cutting in the seeding year for up to 30 days following a non-glyphosate herbicide application, which could sacrifice hay quality.

33. The limitations of non-glyphosate based herbicides used in alfalfa have forced growers to resort to alternative options such as seeding with a companion or nurse crop that may suppress weeds but which also competes with alfalfa, or delaying stand establishment until the fall when weed pressure is reduced. All of these approaches reduce the value of a grower's first year production.

34. Increased yield and quality due to the Roundup Ready alfalfa system results in a significant increase in milk production per acre by dairy cows. Studies show that Roundup Ready alfalfa produces an estimated yield advantage of about 1000 pounds more forage per acre than alfalfa treated with conventional herbicide programs. Not only are alfalfa hay yields increased, but the hay harvested is of superior quality. These increases in yield and quality of alfalfa forage/hay translate into substantially more milk from cows. For example, recent data from multiple locations suggests that cows fed Roundup Ready alfalfa would produce nearly 14% more milk per acre of alfalfa than cows fed alfalfa treated with conventional weed control systems.

35. In addition, glyphosate has been shown to have favorable environmental characteristics (including reduced toxicity) compared to other herbicides. Thus establishment of Roundup Ready alfalfa, which allows

substitution of Roundup branded agricultural herbicides for other herbicides, is expected to reduce the use of more toxic herbicides.

* * *

I declare, under penalty of perjury, that the forgoing is true and correct.

Executed this 1st day of March, 2007 in Salt Lake City, Utah.

/S/
Paulette E. Pierson, Ph.D.

Attorney Signature Attestation

I, Holly J. Tate, counsel for Monsanto Company, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this efiled document.

/S/
Holly J. Tate

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	No. C-06-01075 CRB

DECLARATION OF NEIL HOFFMAN

I, Neil Hoffman, declare as follows:

I make the following representations based upon my personal knowledge and upon facts made known to me in my capacity as an official of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

1. I serve as the Director of the Environmental Risk Analysis Division for the USDA/APHIS' Biotechnology Regulatory Services (BRS). I have been in this position for approximately three and a half years. I have attached a copy of my curriculum vitae as Attachment 1.

Regulation of Genetically Engineered Plants

2. BRS is responsible for the regulation of the importation, interstate movement and release into the environment of genetically engineered (GE) plants.

3. Pursuant to regulations promulgated at 7 C.F.R. Part 340, BRS regulates the introduction of plants and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests in order to prevent the escape, spread, or establishment of plant pests.

4. These regulations allow the confined introduction of GE plants under conditions carefully designed to prevent escape and persistence in the environment. BRS can authorize introductions either under a permit (7 C.F.R. § 340.4) or a notification (7 C.F.R. § 340.3). The regulations also allow an applicant to petition BRS for a determination of nonregulated status (7 C.F.R. § 340.6), if the applicant believes that a regulated plant does not meet the definition of a plant pest.

5. To seek a determination of nonregulated status, the applicant must submit to BRS a petition containing the data specified in section 340.6(c). A regulated article may be granted nonregulated status only upon BRS' determination that it poses no plant pest risk.

Alfalfa Produced in the United States

6. Alfalfa is a perennial herbaceous legume that is grown worldwide, due to its adaptability to a wide range of climates. Alfalfa is grown as forage, where it is consumed by livestock in the field, and for hay, where the edible portions of the plant are mowed and removed for consumption as livestock feed. Alfalfa can be planted either in the spring or fall, depending on the climate and needs of the grower. Established alfalfa stands are typically mowed three to four times per year and can be productive for many years, depending

on climate and crop management. Alfalfa hay is valued for its high levels of protein and other nutrients. Alfalfa hay is especially valued by the dairy industry because of its high calcium content. Hay quality is strongly influenced by crop maturity, and quality declines as flowering commences. Alfalfa is also grown for seed, the majority of which is planted to produce forage and hay. A small portion of alfalfa seed is used for human consumption, as alfalfa sprouts.

7. Growing alfalfa improves the nitrogen content of the soil in which it is planted, and most growers take advantage of this property by rotating alfalfa with other crops that can benefit from the increased soil fertility. Another reason growers plant alfalfa in rotation with other crops is that alfalfa exhibits autotoxicity, whereby alfalfa seeds do not germinate well in established alfalfa stands. Because of this effect, cleared alfalfa fields are not generally reseeded with alfalfa for at least one growing season. The germination of other crop seeds are not affected by alfalfa autotoxicity.

8. Alfalfa is insect pollinated, primarily by honeybees and leafcutter bees. Alfalfa's specialized flower can be pollinated only once, after which it is no longer available to insect pollinators. Producers of alfalfa seed frequently supplement native bee populations with beehives to ensure efficient pollination.

Genetically Engineered Roundup Ready® Alfalfa

9. BRS has many years of experience regulating glyphosate-tolerant Roundup Ready® alfalfa (RRA), which has been genetically engineered for tolerance to the herbicide glyphosate.

10. RRA is genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* sp. strain CP4) that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the alfalfa genome. This gene, along with its regulatory sequences, was introduced into these alfalfa plants via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure, which has been widely used for over two decades for introducing genes of interest directly into plant genomes. BRS has previously granted nonregulated status to other GE glyphosate-tolerant crops, including corn, cotton, soybean, canola and sugarbeet.

11. APHIS first authorized the field testing of RRA in 1998 under its notification procedures (7 C.F.R. 340.3), and has authorized a total of 297 such field trials over a period of approximately eight years.

12. The developers of RRA, Monsanto Company (Monsanto) and Forage Genetics International (FGI), submitted design protocols in 1999 and 2000 that describe how field trials of RRA would be managed to comply with the performance standards required for all GE crops released under authorized notifications. These performance standards require that any field trials be conducted in a manner such that the GE plants are confined effectively and will not persist in the environment at the conclusion of the field trial.

13. The design protocols included maintaining a buffer zone of at least 900 feet between the RRA and other alfalfa, or keeping flowering plants in cages to preclude access to pollinators, or mowing alfalfa plantings to prevent the development of flower buds.

14. These protocols also required that any farm equipment used on RRA that could retain reproductive parts of the alfalfa plant had to be cleaned after use in the field where the RRA was grown, to avoid spreading reproductive parts to other areas. When field trials were terminated, RRA was destroyed using an appropriate herbicide, and the plant debris was incorporated into the soil by disking. Fields planted with RRA were monitored for a minimum of one full growing season after the termination of all field trials. Lastly, all fields used for the testing of RRA were clearly labeled for a full growing season after the termination of the field trial. Field trials of RRA were subject to routine inspections by BRS, and throughout the eight year period Monsanto and FGI maintained a good compliance record.

Granting Nonregulated Status To Roundup Ready® Alfalfa

15. On April 16, 2004, BRS received a petition from Monsanto and FGI requesting a determination of nonregulated status under RRA. On November 19, 2004, BRS completed its draft environmental assessment (EA). On November 24, 2004, a Notice was published in the *Federal Register* (69 FR 68300-68301), advising the public that BRS received Monsanto's petition, soliciting public comments on whether RRA presents a plant pest risk, and making available the EA for public comment. The comment period closed on January 24, 2005, but was reopened and extended to February 17, 2005, to provide interested parties additional time to comment (70 FR 5601-5602). BRS received 663 comments by the close of the extended comment period. There were 127 comments in support

of the petition and 520 in opposition to the petition. BRS finalized the EA and the Finding of No Significant Impact (FONSI) was signed on June 14, 2005. On June 27, 2005, BRS published in the *Federal Register* a Notice advising the public of its determination of nonregulated status, which was effective on June 14, 2005, and also announcing the availability of BRS' written determination document and FONSI. (70 FR 36917-36919). The decision to grant RRA nonregulated status was based, in part, on data included in the petition demonstrating that RRA posed no plant pest risk.

16. Since June 14, 2005, RRA has not been regulated by BRS under 7 C.F.R. Part 340. Therefore, after that date, RRA could be grown, sold, and processed in the United States without BRS oversight.

17. Plaintiffs filed this lawsuit on February 16, 2006, approximately eight months after BRS granted RRA nonregulated status.

18. Since being granted nonregulated status, there have been at least three planting cycles of RRA. Based upon information provided by Monsanto and FGI, approximately 220,000 acres of RRA have been planted by greater than 3,000 growers in 48 states since RRA was granted nonregulated status. Approximately 75 of these growers grow RRA for the production of alfalfa seed; the remainder are growing it exclusively for hay and forage. RRA constitutes approximately one percent of the total alfalfa acreage in the United States. Based on current sales, grower planting intentions, and available inventory, Monsanto would anticipate an additional 350,000 acres in new RRA forage production in 2007.

19. Because alfalfa stands are productive for many years, there are no commercial plantings of RRA old enough to justify destruction due to declining productivity.

Harm to Growers if RRA is Required to be Destroyed

20. The information presented below with respect to estimates of harm has been drawn from a variety of sources, including Monsanto and FGI, publically available information and information known to me in my capacity as an official of BRS. More comprehensive information regarding the extent of potential harm would need to be obtained from all of the affected agricultural sectors.

21. If growers of RRA were required to prematurely destroy their crop, they would suffer significant economic losses. The grower's investment in seed, fuel, fertilizer, pesticide, irrigation costs and labor is lost if the grower is unable to harvest alfalfa throughout the full usable lifespan of the crop. Most of these expenses are incurred in the first year of production to establish the crop while returns are realized over the ensuing years of production. Further, if a forage producers' crop is destroyed, the producer would be required to purchase livestock feed from another source. Persons who are growing RRA for hay would lose anticipated sales. As noted above, cleared alfalfa fields are not generally reseeded with alfalfa for at least one growing season. Therefore, growers forced to prematurely destroy their alfalfa may suffer loses attributable to growing an alternative crop.

22. Estimated data provided by Monsanto shows that to remove the existing RRA crop of 220,000 acres,

growers would lose an estimated $144,000,000 for expenditures in 2006 and lost production in 2007 based on a cost of $654 per acre assuming per acre costs as follows:

A. Equipment/labor (for crop destruction)	$ 50
B. Lost seed investment	$ 102 ($6/1b @ 17 lbs/acre)
C. Lost herbicide	$ 12
D. Lost production	$ 490 (5 tons/acre @ $140/ton minus $210 maintenance)

Maintenance costs are estimated from an economic analysis by the Oklahoma Cooperative Extension Service (OK Cooperative Extension Service Document Number E826 (http://www.okstate.edu/OSU_Ag/agedcm4h/pearl/e826/ch2.htm). Assuming similar production returns and maintenance costs, if farmers cannot plant RRA in 2008, they may lose up to $108,000,000 ($490/acre x 222,000).

23. If a grower is required to prematurely destroy an alfalfa planting, necessary equipment ordinarily leased by the grower may not be available at the time of the destruction. The fields may not be in a condition appropriate for cultivation at the time of destruction, thus resulting in degradation of soil quality, soil erosion, and other damage that could negatively impact the environment.

Harm to Growers if Future RRA Production is Enjoined

24. Growers who anticipated planting RRA will be unprepared for the coming growing season. Based on information provided by Monsanto and/or FGI, growers expect $100 to $200 per acre, on average, in

value over conventional alfalfa over the life of the RRA crop. New grower interest was high and current users anticipate increasing RRA acreage to approximately 570,000 total acres during the 2007 growing season. In anticipation of the spring 2007 planting season, growers may have already purchased their RRA seed and would have to substitute conventional seed if planting RRA in the next growing cycle is prohibited.

Harm to Monsanto and FGI if Future RRA Production is Enjoined

25. According to Monsanto and FGI, most of the seed produced in 2006 has been purchased by seed companies, distributors, dealers and/or growers. Without opportunity for planting, Monsanto and FGI seed companies and dealers will lose an economic return on seed investment of approximately $35,000,000. The value of the RRA seed to be harvested in fall 2007 is approximately $50,000,000. Also to be considered is the overall impact on the availability (See Appendix I, p. 328 of the petition, http://www.aphis.usda.gov/brs/aphisdocs/04 11001p.pdf) of alfalfa seed for planting over the next three years. Information submitted to BRS regarding seed production shows that production of commercial seed for alfalfa varieties is a multi-year process (up to three years minimum). FGI is the world's largest alfalfa seed production and breeding company. After being granted nonregulated status, the RRA could be freely crossed into different alfalfa varieties without BRS oversight. Significant resources have been devoted to breeding efforts targeted in developing varieties and increasing alfalfa seed that include the RR trait. Many of the seed producers have based varietal development plans on the assumption that

RRA will remain nonregulated. Seed producers and dealers would be forced to hold or destroy substantial inventories of RRA seed with immediate adverse impact on their businesses.

Harm to Exports if RRA Loses Nonregulated Status

26. Generally, countries will not allow importation of GE crops unless those crops have been granted nonregulated status or otherwise approved by the country of origin. If RRA is no longer considered a nonregulated article, alfalfa exports may be disrupted. Approximately 1.3 percent of the domestic alfalfa hay crop was exported in 2006. As the court noted, 75 percent of the alfalfa exported from the United States is exported to Japan. In March of 2006, Japan decided to allow the importation of RRA. If RRA is once again considered regulated by the United States, Japan may reconsider its decision. Even if exports of non-RRA were allowed to continue, foreign countries may require that alfalfa be tested for the presence of RRA which would cause exporters to incur costs associated with conducting the tests and evaluating the results. If foreign markets are closed, the unsold alfalfa could result in unexpected and harmful price fluctuations on the domestic market.

27. The uncertainty of the status of RRA will likely create general confusion and a lack of confidence among trading partners regarding past and future determinations of nonregulated status of GE plants by BRS. Acceptance of exports would be undermined and could result in enormous harm to growers who plant GE crops other than RRA. Importing countries may impose testing requirements for the presence of GE

traits, causing exporters to incur additional associated costs.

Risk of Gene Flow and Stewardship Practices —Likelihood of gene flow in alfalfa forage and hay production

28. The quality, and therefore the value, of alfalfa hay decreases with the onset of flowering and seed formation, and growers obtain significantly higher prices for hay cut prior to flowering as opposed to hay cut while plants are in full flower. Because of this price differential, alfalfa hay is often harvested prior to flowering and most always prior to seed set (Intermountain Alfalfa Management. UC Davis, Division of Agriculture and Natural Resources. Publication 3366, chapter 11. Harvest Management). According to statistics compiled in 2006, the price differential for high quality alfalfa was even greater for organic hay than for conventional hay, thereby encouraging mowing prior to flowering and seed set. (Alfalfa Hay 2006, CA Market Summary; http://www.ams.usda.gov/lsmnpubs/PDF_Monthly/2006CAHay.pdf).

29. Some pollen will be produced by fields harvested at 10% bloom, but this pollen has no effect on established plants. There is no biological means by which pollen can change the genetic constitution of an established plant. Pollen can fertilize the ovules within the flowers of existing plants to yield seeds with the GE trait. However, fields that do not produce seeds have no potential for gene flow and typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will produce any seeds.

30. According to Daniel Putnam, Extension Agronomist at University of California, Davis (Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf), gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage will be negligible for several reasons. First, flowering must be simultaneous between the proximate fields, and this is unlikely because there are many different alfalfa varieties, and they flower at different times. Second, sufficient pollinators must be present, they must move significantly between the two fields, and they must successfully transfer pollen from a flower in one field to a flower in another field. This series of events is unlikely because alfalfa grown for hay or forage is not stocked with bees to encourage pollination. Third, fertile embryos must mature into seeds, fall to the ground, and germinate, in spite of competition from mature alfalfa plants and the effects of autotoxicity, to contribute significantly to the dry matter of the subsequent hay crop.

31. Alfalfa is grown as a perennial crop for up to eight years. As long as seed used to plant the conventional or organic field is GE free, and the crop is managed for forage or hay, no measurable GE contamination should occur in the crop over the lifetime of that planting.

—Likelihood of gene flow from RRA forage fields to conventional seed fields

32. Intermingled alfalfa hay and alfalfa seed production only occurs in a few western states which

have the specific climate required for successful commercial seed production. Certified alfalfa seed production requires 165 feet of isolation from hay production employing other varieties. The isolation is inspected and verified by state seed certification organizations or an accredited organic certifier. Some conventional hay/forage fields are allowed to go to seed to produce "common seed." To minimize gene flow from RRA hay fields to common seed fields which are not certified, RRA hay growers are required to harvest at or before 10% bloom. (*See*, RRA stewardship practices, *infra*) As neither forage fields nor common seed fields are stocked with bees and forage fields contain few blooms to attract native pollinators, the potential for pollen-mediated gene flow to common seed fields is minimal.

33. Estimates of pollen-mediated gene flow from forage fields to seed fields have been made in a "worst case" forage management situation where the forage fields were allowed to flower more extensively than would commonly occur when alfalfa is managed for hay production. In addition, the seed fields were stocked with pollinators which also is not the usual practice for common seed production. In one case flowering was allowed to occur to 50% bloom in a neighboring hay field and leaf cutter bees were used to pollinate seed fields situated at increasing distances from the flowering field. In this case gene flow was 0.2% at both 150 and 300 feet. In a second study, flowering in the neighboring hay field was allowed to occur to 20% bloom and honey bees were used to pollinate the seed field. In this case, gene flow was 0.29% at 165 feet, 0.16% at 215 feet, 0.15% at 315 feet and was rarely

detected (0.00 to 0.05%) at distances greater than 350 ft.

—Likelihood of gene flow in alfalfa seed production

34. Approximately 18,000 acres of RRA have been planted for seed production since June, 2005, when RRA was granted nonregulated status.

35. An alfalfa pollen flow study was conducted during the summer of 2000 by FGI, in association with members of the Regulatory Affairs Committee of the North American Alfalfa Improvement Conference (McCaslin, M. and S. Fitzpatrick 2000, 37th NAAIC proceedings, pp. 396-400). Fields were stocked with leaf cutter bees and also contained native honey bees. Pollen flow was estimated as 1.39, 0.32, 0.07, and 0.00 percent at 500, 1000, 1500, and 2000 feet, respectively. Results from this experiment indicate that gene flow will be under 0.5% in adjacent alfalfa fields if isolation distances of 900 feet are maintained when leaf cutter bees are used as the pollinator.

36. Leaf cutter bees are the predominant pollinator for alfalfa in all western states except California where honeybees are used instead.

37. An alfalfa pollen flow study was conducted during the summer of 2002 in California by University of California, Davis, FGI and Monsanto. Fields were stocked with honeybees. Pollen flow was estimated as 1.49, 1, 0.2, and under 0.06 percent, at 900, 3000, 5000, and 10,000 feet, respectively. Results from this study indicate that gene flow will be under 0.1% in adjacent alfalfa fields if isolation distances of 3 miles are maintained when honey bees are used as the pollinator.

—RRA stewardship practices

38. To facilitate coexistence between RRA growers and other alfalfa growers, Monsanto and/or FGI require all RRA growers to sign an agreement which requires the RRA grower to follow strict stewardship practices. All seed purchasers, dealers, distributors, producers and processors of RRA seed must be licensed by Monsanto and agree to comply with such stewardship practices. Therefore, Monsanto and/or FGI have records of all growers and site locations of RRA in the United States.

39. Forage growers are provided with online training modules. Grower agreements limit planting of purchased seed to the United States and obligate all participants to limit seed use to the planting of RRA for hay and forage (seed production is prohibited). In areas where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, RRA must be harvested at or before 10% bloom to minimize potential pollen flow from hay to common alfalfa seed production.

40. All growers who purchase RRA in states where alfalfa seed is produced are required to report to Monsanto the field locations and global positioning coordinates for any field planting of RRA. Alfalfa seed-producing states include the following 17 states; AZ, CA, CO, ID, KS, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WY. This information is intended to be used to audit forage producers to ensure that no unauthorized seed production is occurring and that they are mowing their hay prior to 10% bloom.

Following the first year of launch, Monsanto will conduct on farm spot checks and contacts growers to ensure compliance with the limited-use license agreement. Failure to comply with that license or the stewardship requirements will result in termination of an RRA grower's limited-use license and a restriction on the future use of Monsanto products.

41. All seed production is sub-contracted through FGI. All growers receive annual training and on-farm support. FGI requires that all growers of RRA seed be under a seed production contract for each variety. Contract seed growers are prohibited from selling RRA variety seed into "common" or "VNS" seed channels. Foundation seed standards are the standards established by the Association of Official Seed Certifying Agencies (AOSCA). FGI requires foundation seed standards for isolation (900 feet) in areas where leaf cutter bees are used for pollination and 3 miles in areas where honey bees are used (e.g., in California). Isolation distances are verified by state crop improvement associations. In the western United States, where hay and seed are both produced, licensees must identify the exact field location where RRA seed will be planted. Monsanto monitors for potential violations.

42. Harvested seed is placed in unique RRA seed bins. RRA seeds have a unique purple seed coating to distinguish them from conventional varieties and seed is processed under license only in a limited number of facilities. Seed bags are labeled "Roundup Ready® alfalfa." All seed purchasers, dealers, distributors, producers, and processors of RRA seed are licensed through Monsanto.

43. FGI seed growers report all RRA seed production field locations to state crop improvement associations to facilitate the industry's management of field history and isolation information. FGI grows all RRA variety seed in the United States using AOSCA and/or Organization for Economic Cooperation and Development certification standards.

44. Seed producer contracts prohibit the sale of RRA seed for sprouting (food) use. However, food safety consultation with the United States Food and Drug Administration were completed and covered the incidental inadvertent presence of the RRA trait in seed used for sprouting purposes.

45. To support buyer-seller agreements that may stipulate conditions for GE trait status, trait detection strips are readily available for alfalfa seed and hay product and are simple to use.

46. For the reasons stated above, I believe that gene flow is negligible between hay fields due to (1) the biology of alfalfa plants; (2) management practices driven by the value and quality of the crop; and (3) stewardship requirements imposed by Monsanto and FGI. Accordingly, there is little possibility of harm to plaintiffs.

BRS' Ability to Re-Regulate RRA

47. BRS approves a petition for nonregulated status when it concludes that the GE plant poses no plant pest risk. Once BRS has granted nonregulated status, the GE plant may be freely moved and planted without the requirement of permits or other regulatory oversight. In this case, BRS determined that RRA poses no plant pest risk, no information has become available subsequently to alter that conclusion, and the

opinion of the Court in this case does not set aside that determination. In the administrative record and the record of this proceeding, there is no demonstrated threat of harm to plant health, human health or livestock health from RRA.

48. If BRS were required to fully re-regulate the RRA that has been planted to date, it would pose significant practical difficulties. The current permitting system is designed to regulate small scale field tests and plants are required to be destroyed at the conclusion of the field tests. Issuing permits for 220,000 acres of RRA planted for forage/hay production would be impracticable. The inspection of such large acreage under permit would pose unusual challenges to BRS' current regulatory structure and significantly drain BRS resources. Furthermore, BRS would be responsible for issuing permits for the interstate movement of all hay, seeds and other RRA products produced on the thousands of acres of RRA grown under permit.

49. Further, as a policy matter, because BRS' determination that RRA poses no plant pest risk is still operative, it would be illogical to regulate RRA pursuant to a permitting scheme that is designed to mitigate plant pest risks. In accordance with this Court's opinion, BRS is fully committed to prepare a comprehensive environmental impact statement prior to deciding in the future whether RRA should be unconditionally deregulated. BRS believes that it would take approximately two years to complete the environmental impact statement. In the interim period, BRS proposes that RRA should be allowed to be grown, harvested and used, but only in accordance with the following stringent, science-based

requirements which are designed to address the potential environmental harms identified by plaintiffs and this Court. This course of action is consistent with the determination that RRA is not a plant pest and would be less likely to result in foreign trade disruptions.

50. BRS proposes the following conditions for RRA planted after the date of this judgment:

a. Isolation distances between RRA and alfalfa seed production fields will be required to mitigate any potential pollen flow;

b. Specific harvesting conditions for RRA fields will be required to minimize cross pollination in areas where growers are producing alfalfa seed;

c. Cleaning of planting and harvesting equipment will be required after contact with RRA prior to its use on non-RRA alfalfa;

d. Identification and handling requirements for RRA seed before and after harvest;

e. All RRA seed producers and hay growers must be under contract, with Monsanto and/or FGI and the contracts must require compliance with the four preceding conditions and these conditions must be followed for the entire life of the RRA stand; and.

f. No RRA can be used for livestock grazing purposes or in a mixed grass pasture.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 2nd day of March, 2007, in Riverdale, MD.

/s/ Neil Hoffman
NEIL HOFFMAN

NEIL HOFFMAN, Ph.D

EDUCATION

Ph.D., Plant Physiology, University of California, Davis, CA, 1982

- Thesis: Regulation of Ethylene Biosynthesis

B.Sc., Biology, Cornell University, Ithaca, NY, 1978

EXPERIENCE

USDA. Animal Plant Health Inspection Service. Biotechnology Regulatory Services.
Riverdale, MD. **2003-present**
Director of Environmental Risk Analysis Division.

NATIONAL SCIENCE FOUNDATION, Arlington, VA. **2002-2003**
Program Director, Division of Cellular and Molecular Biology

PARADIGM GENETICS, RTP, NC **1999 - 2002**
Senior Staff Scientist/Manager of Plant Physiology and Biochemistty

CARNEGIE INSTITUTION of WASHINGTON, Stanford, CA **1988 -1999**
Associate Professor of Plant Biology, Stanford University, Dept. of Biology 1996 - 1999
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Postdoctoral Research Associate with Andrew Hanson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	) No. C-06-01075 CRB

SECOND DECLARATION OF NEIL HOFFMAN

I, Neil Hoffman, declare as follows:

I make the following representations based upon my personal knowledge and upon facts made known to me in my capacity as an official of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

1. I serve as the Director of the Environmental Risk Analysis Division for the USDA/APHIS' Biotechnology Regulatory Services (BRS). On March 2, 2007, I provided a declaration to this Court.

2. As indicated in my first declaration, APHIS is fully committed to preparing a comprehensive environmental impact statement (EIS) prior to deciding in the future whether RRA should be unconditionally deregulated. APHIS believes that the EIS will take approximately two years to complete.

3. APHIS approves a petition for nonregulated status only after it concludes that the GE plant poses no plant pest risk. Because APHIS' determination that RRA poses no plant pest risk is still operative, it would be illogical to regulate RRA pursuant to a permitting scheme that is designed to mitigate plant pest risks. Further, the current permitting system is designed to regulate small scale field tests. Issuing permits for 220,000 acres of RRA planted for forage/hay production would be impractical. Additionally, inspecting such large acreage under permit would significantly drain APHIS resources. Therefore, prior to APHIS' completion of the EIS, APHIS proposes that RRA can be grown, harvested and used, provided it is in accordance with six stringent, science-based requirements designed to mitigate the potential environmental harms specified by this Court. This course of action is consistent with the determination that RRA is not a plant pest and would be less likely to result in foreign trade disruptions.

4. I am providing this supplementary declaration to further explain the six requirements set forth in ¶ 50 of my first declaration. These requirements are in addition to current Monsanto/FGI stewardship and contract requirements, and would apply to RRA planted after the date of this Court's judgment. These requirements mitigate pollen-mediated and seed-mediated gene flow and possible routes of commingling. In designing these requirements, APHIS considered that the risk of gene flow between alfalfa hayfields is negligible because market forces prompt producers to harvest prior to seed formation; typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will

produce any seeds; and fields that do not produce seeds have no potential for gene flow.

5. Furthermore, according to Daniel Putnam, Extension Agronomist at University of California, Davis *(see* Attachment #1: Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf), gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage will be negligible for several reasons. First, flowering must be simultaneous between the proximate fields, and this is unlikely because there are many different alfalfa varieties and they flower at different times. Second, sufficient pollinators must be present, they must move significantly between the two fields, and they must successfully transfer pollen from a flower in one field to a flower in another field. This series of events is unlikely because alfalfa grown for hay or forage is not stocked with bees to encourage pollination. Third, fertile embryos must mature into seeds, fall to the ground, and germinate, in spite of competition from mature alfalfa plants and the effects of autotoxicity, to contribute significantly to the dry matter of the subsequent hay crop.

6. Alfalfa is grown as a perennial crop for up to eight years. As long as seed used to plant the conventional or organic field is GE free, and the crop is managed for forage or hay, no measurable GE contamination should occur in the crop over the lifetime of that planting. The following proposed requirements largely mitigate gene flow to conventional and organic seed production.

7. **ONE, APHIS will require isolation distances between RRA and alfalfa seed production fields to mitigate any potential pollen-mediated gene flow.**

(a) APHIS will require that pollinators shall not be added to RRA fields grown only for hay production. Without pollinators, pollen-mediated gene flow is considerably less for insect-pollinated crops compared to when the pollinators are present *(see* Attachment #2: Van Deynze, A.E. and K.J. Bradford. 2005. Pollen-mediated gene flow in California cotton depends on pollinator activity. Crop Science. 45:1565-1570).

(b) APHIS will require that growers of RRA identify and keep records of all alfalfa crops being grown within 500 feet of their fields. If alfalfa fields are located within this isolation distance, growers of RRA have specific stewardship requirements, which include preventing flowering in any RRA field within 165 feet from another alfalfa seed field and harvesting at 10% bloom any RRA field located between 165 and 500 feet from another alfalfa seed field.

(c) APHIS will require specific isolation distances, based upon the best scientific knowledge and cultural practices, for the following activities:

(1) When RRA is grown for hay production, APHIS will require that RRA be planted 165 feet from any alfalfa fields used for certified seed production. For an experiment using pollinators in a seed field and a hay field containing more blooms (i.e., 20-50%) than will be allowed by this judgment, an isolation distance of 165 feet was found to reduce pollen-mediated gene flow to under 0.2% for leaf cutter bees and 0.3% for honey bees *(see* Attachment #3: Teuber, L.R. and S.N. Fitzpatrick. 2007. Proceedings of the Alfalfa Seed

Production Symposium, March 5-6, 2007. San Joachin and Holtville, CA (in press)). Experiments with honeybees show that they fly no further than is necessary to obtain sufficient food. As the number of alfalfa blooms at a given time increases, the amount of bee movement between flowers decreases *(see* Attachment #4: Strickler, K. 1999. Impact of flower standing crop and pollinator movement on alfalfa seed yield. Population Ecology 28: 1067-1076, http://www.entsoc.org/pubs/ee/eetocs/PDF/en069901067p.pdf). As the percent bloom increases in a hay field, the hay field becomes more attractive to bees and increases the likelihood that bees will leave a seed field to forage in a hay field resulting in increased pollen-mediated gene flow. For this reason, the experiment mentioned above, using fields of 20-50% bloom overestimates the pollen-mediated gene flow expected in a field harvested prior to 10% bloom.

(2) When RRA is grown for seed production, APHIS will require that RRA be planted using the following isolation distances: 1500 feet from any alfalfa fields used for seed production, when leaf cutter bees are used to pollinate RRA; and 3 miles from any alfalfa fields used for seed production, when honey bees are used to pollinate RRA. The isolation distance of 1500 with leaf cutter bees was found to reduce pollen-mediated gene flow to under 0.1% *(see* Attachment #5: McCaslin, M. and S. Fitzpatrick 2000, 37th NAAIC proceedings, pp. 396-400, http://naaic.org/Meetings/National/2002meeting/2002Abstracts/Fitzpatrick.pdf). The isolation distance of 3 miles with regard to honey bees was found to reduce pollen-mediated gene flow to under 0.1% *(see* Attachment #6: Teuber, L.R., et al. 2004. Gene flow in

alfalfa under honeybee *(Apis mellifera)* pollination (Abstract). 39th NAAIC, http://naaic.org/Meetings/National/2004NAAIC&TC/2004abstracts/lteuber.pdf). The Association of Official Seed Certifying Agencies (AOSCA) establishes minimum standards for genetic purity, identity, and seed quality. In the United States, there are four seed classes designated: Breeder, Foundation, Registered, and Certified. Breeder seed is directly controlled by the plant breeding institution and is used to produce Foundation seed under strictly controlled conditions. Similarly, Foundation seed is used to produce registered seed. Certified seed may be produced from either Foundation or Registered seeds. For alfalfa, AOSCA standards require Foundation, Registered, and Certified seed to be produced with an isolation distance from any other alfalfa of 900, 450, and 165 feet, respectively. These distances are used to ensure 99.90, 99.75, and 99% varietal purity for the respective classes. When a grower purchases high quality varietal seed to produce a hay crop, that seed is usually Certified seed. Currently RRA seed is being produced for growers as Foundation seed. This seed is currently being produced under conditions in excess of the customary standards for genetic purity. The 1500 foot isolation distance now exceeds even that used to produce Foundation seed. In other words, the proposed isolation distance for seed production vastly exceeds the standards used for commercial seed production.

8. **TWO, APHIS will require specific harvesting conditions for RRA fields to minimize gene flow, especially in areas where growers are producing common alfalfa seed.**

(a) APHIS will require that all RRA hay fields be harvested prior to seed set. This measure will eliminate seed-mediated gene flow from the hay fields *(see* Attachment #1). Some pollen will be produced by fields harvested at 10% bloom, but this pollen has no effect on established plants. There is no biological means by which pollen can change the genetic constitution of an established plant. Pollen can fertilize the ovules within the flowers of existing plants to yield seeds with the GE trait. However, fields that do not produce seeds have no potential for gene flow and typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will produce any seeds.

(b) APHIS will require that RRA fields located within 165 feet of any alfalfa field grown for common seed production shall be harvested pre-bloom. This measure will eliminate any gene flow from RRA hayfields to common seed fields located within 165 feet.

(c) APHIS will require that RRA fields located between 165 and 500 feet from any alfalfa field grown for seed production shall be harvested at or before 10% bloom. Combined with the measures to restrict stocking hayfields with pollinators and preventing bloom within 165 feet, these measures will ensure that pollen-mediated gene flow to any common seed production is below 0.1%. Beyond 500 feet, pollen-mediated gene flow from hay fields to common seed fields is essentially zero *(see* Attachment #3).

9. **THREE, APHIS will require that farm equipment used in RRA production be properly cleaned after use.** Some farm equipment may be shared between RRA and conventional alfalfa. The

below measures minimize the spread of RRA through shared farm equipment. Alfalfa is propagated via seed; it is very difficult to propagate alfalfa from other tissues such as roots, stems, and leaves. Drying of the leaves and stems into hay kills the plant making it nonviable. RRA hay must be harvested prior to seed set making it unlikely that any viable seed will be present in the hay. The three cleaning conditions below aim to reduce the amount of seed that is caught in equipment that is shared with conventional alfalfa. Seed may be trapped in machinery such as planters or attached to the wheels of planters, harvesters, tractors or tillage equipment. As RRA must be harvested prior to seed set, it is unlikely that harvesters will be contaminated with viable seeds. However, a small amount of non-viable hay may remain in harvesters after use. To eliminate the possibility that this hay will be bundled with conventional alfalfa, harvesters will be required to be cleaned before use in conventional alfalfa fields or before it leaves the farm on which it came in contact with RRA.

(a) APHIS will require that cleaning procedures for planters, harvesters, tractors and tillage equipment be submitted to and approved by APHIS prior to implementation.

(b) APHIS will require that cleaning procedures be designed to minimize the risk of RRA seed and hay movement from the authorized production site.

(c) APHIS will require that all equipment be cleaned before it leaves the farm on which it came in contact with RRA.

10. **FOUR, APHIS will require that RRA be handled and clearly identified to minimize**

commingling after harvest. APHIS will require that, immediately after harvest, RRA seed must be stored in specifically designated and clearly labeled containers until seed is transferred to FGI. Potential mishandling of RRA can be minimized by imposing measures to clearly identify RRA from conventional alfalfa. By requiring RRA to be stored in specially designated and clearly labeled containers, handlers will be less likely to confuse RRA with conventional alfalfa.

11. **FIVE, APHIS will require that RRA shall not be used for livestock grazing purposes or in a mixed grass pasture.** This condition is being imposed to restrict management options that might complicate harvest requirements. Animals left to graze a field may not uniformly eliminate flowering. Similarly, flowering in a mixed grass pasture may not be as uniform among the different species and the effect on pollinators less predictable. To reduce the potential loss of control in these management options, livestock grazing and mixed pasture use will be restricted.

12. **SIX, APHIS will require that all RRA seed producers and hay growers must be under contract with Monsanto or FGI.** These contracts must require compliance with the five preceding conditions, and these conditions must be followed for the entire life of the RRA stand. Contractual agreements have explicit obligations that must be met by the grower and Monsanto that help ensure compliance with stewardship agreements and terms of the judgment. Some of these terms facilitate co-existence. For example, Monsanto will collect and share with APHIS all growers' GPS information. Such information will enable Monsanto, FGI and APHIS to conduct on-farm inspections to verify compliance with isolation

distances and harvest requirements. Contracts require annual training for RRA seed producers. Seed production contracts also specify strict conditions for the production, handling and distribution of seed including identity preservation protocols. For example, contractor seed growers report all RRA seed production field locations to state crop improvement organizations to facilitate the industry's management of field history and isolation information. FGI grows all RRA variety seed in the United States using AOSCA and/or Organization for Economic Cooperation and Development certification standards. RRA seeds have a unique purple seed coating to distinguish them from conventional varieties and seed is processed under license only in a limited number of facilities. Seed bags are labeled "Roundup Ready® alfalfa." Seed producer contracts prohibit the sale of RRA seed for sprouting (food) use. In this way, contractual agreements facilitate compliance with the terms of the judgement.

13. Accordingly, implementation of these six requirements to RRA planted after judgement would address the potential harms identified by this Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ___ day of March, 2007, in Riverdale, MD.

/s/ Neil Hoffman
NEIL HOFFMAN

[Division of Agriculture and Natural Resources, University of California logo omitted]

AGRICULTURAL BIOTECHNOLOGY IN CALIFORNIA SERIES PUBLICATION 8193

Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa

DANIEL H. PUTNAM, Extension Agronomist, Department of Plant Sciences, University of California, Davis

During the past decade, genetically engineered (GE) traits have been successfully commercialized in corn, cotton, canola, papaya, squash, and soybean, particularly the Roundup Ready (RR) trait that allows the herbicide glyphosate (Roundup) to be applied to kill weeds without damaging the crop. In June 2005, alfalfa *(Medicago sativa)* varieties with the RR trait were deregulated (APHIS 2005), allowing GE alfalfa varieties to be sold commercially.

In recent years, alfalfa has overtaken wheat as the third most important crop economically in the United States, exceeded only by corn and soybeans. Over 22 million acres (8.9 million ha) are harvested each year, with the largest alfalfa-producing states in the Midwest and West, particularly California, South Dakota, Wisconsin, Idaho, Minnesota, and Iowa (NASS 2005). Alfalfa is California's largest crop by area at 1.05 million acres (425,000 ha), with a value of $800 million to $1 billion. California produces more alfalfa hay than any other state.

When fully commercialized and if adapted by growers, the RR technology may cause profound

changes in the way alfalfa growers approach weed control as well as in the varieties that they grow (Van Deynze et al. 2004). However, the introduction of GE alfalfa varieties may also pose challenges to their coexistence with non-GE and organic production and marketing systems (Pridham 2004).

What are the sensitivities of alfalfa markets and consumers?

Crops with GE traits such as the RR trait or resistance to insects using *Bacillus thuringiensis* (Bt) have been used in animal feeding systems for more than a decade, and a number of studies have shown that DNA or proteins from GE crops have not been detected in milk, meat, eggs, or other products from animals that consume these crops (FASS 2005). Government agencies, using the concept of "substantial equivalence" to judge the safety of GE crops have concluded that RR alfalfa is safe to enter the U.S. animal feed market (APHIS 2005). Despite these assurances, some markets are sensitive about the presence of GE traits in alfalfa and wish to maintain alfalfa crops that do not have GE traits.

How is alfalfa used?

While precise alfalfa use patterns in the United States are not known, alfalfa hay has three major markets: dairies, beef, and horses, with minor uses for export, small ruminants (sheep and goats), processed feeds, and alfalfa pellets for pets and rabbits. The market for alfalfa seed presents separate and important issues with regards to GE traits (Mueller 2004), but its scope is smaller in acreage and more localized in western states. The potential for the RR trait to impact the

market for hay is described briefly in this publication and was considered in more detail in Putnam 2004b.

Will dairies use genetically engineered alfalfa?

Of the three major uses of alfalfa forage, dairy is clearly the driving force for U.S. alfalfa production. In California, alfalfa for dairy use may consume more than 75 percent of production, and alfalfa is often considered the staple of U.S. dairy production. Alfalfa is either raised by dairies and fed on-farm or raised independently and sold to dairies; these two systems have major differences in terms of marketability and acceptance. For on-farm use, marketing issues are confined largely to views of the dairy producer and the marketers of milk. For cash hay producers, market signals are manifest through price and willingness to buy.

It is anticipated that the dairy industry will not, with some notable exceptions, be highly sensitive to the presence of a GE trait in alfalfa. The dairy industry has already absorbed a sizable number of GE technologies that are currently components of milk production systems:

- *bovine somatotropin* (BST), a naturally occurring hormone produced via GE methods, which has been in use as a supplement for over 10 years
- Roundup Ready and Bt crops, particularly corn, soybean, canola, and cottonseed meal, all of which feature prominently in dairy feed rations
- cheese produced with rennin (chymosin) from GE bacteria

These GE traits in the dairy system have by and large not proved to be major marketing issues for dairies.

The exception is organic dairy producers, who have rejected GE crops as a component of organic certification (NOP 2005). Organic milk is a small but growing component of U.S. milk production, with the number of certified organic milk cows having increased by 277 percent from 1997 to 2001 but still constituting less than 1 percent of total U.S. milk production (Miller 2005). Organic dairy producers demand hay originating not only from non-GE alfalfa but also from fields approved for certified organic crop production.

Will horse owners use genetically engineered alfalfa?

Alfalfa and alfalfa-grass mixtures are the most important hay crop for the U.S. horse industry (Shewmaker et al. 2005). It has been estimated that there are 650,000 horses in California (Rodiek 2004). Horses are likely to be significant consumers of alfalfa, but the exact size of this market is not known. Horse owners are individual buyers, each with their own prejudices that likely influence their hay-buying decisions, a situation markedly different from the dairy and beef industries (Rodiek 2004; Lawrence 1998). As a result, it is probable that some horse owners will resist feeding RR alfalfa, but this is also not likely to be universal. Important to consider is the fact that sizable numbers of horses are sickened or die from poisonous weeds in hay each year (Pushner 2004), a quality aspect that may tip customer preference in favor of RR alfalfa over time.

Will the beef, sheep, and goat industries use genetically engineered alfalfa?

The quantity of alfalfa used in the beef industry is not known, but a larger percentage of nonalfalfa forage is

fed to beef cattle than to dairy cattle. Less than 1 percent of beef production is organic (NCBA 2005); however, for the reasons described above for dairy, it is unlikely that most beef producers will be sensitive to GE alfalfa. Food safety concerns with beef are generally more focused on specific disease issues (e.g., BSE, or mad cow disease), or on the use of antibiotics or chemicals. Organic beef requires non-GE hay. GE (or even conventional) alfalfa will not be important for grass-fed beef (another marketing category) for obvious reasons. Sheep and goat enterprises are tied to ethnic or specialty uses and may be more sensitive than beef to GE alfalfa, but the quantity of alfalfa used by this sector is very small.

What effect will genetically engineered alfalfa have on exports?

It is clear that the majority of exporters will be sensitive to the presence of GE alfalfa, at least in the initial few years of production. Across six western states, over 800,000 metric tons (881,000 t) of alfalfa, or 4.5 percent of production, is exported (table 1). Less than 1 percent of U.S. alfalfa is exported, and other classes of hay (e.g., sudangrass, timothy) now exceed exports of alfalfa. However, in some regions, such as the Imperial Valley of Southern California and in central Washington, the percentage of alfalfa grown for export is higher. In these regions, growers may export only one or two cuttings of their hay per year, but the exporter's acceptance impacts the grower's variety decision for the whole production season. Japan is the dominant recipient of U.S.-grown hay. Exporters in many cases have insisted on written contracts in which producers guarantee non-GE alfalfa. In 2005, growers who purchase the RR trait license had to restrict their

hay production to domestic use, and seed sales have been restricted in regions such as the Imperial Valley and central Washington where exports are important. Roundup Ready alfalfa hay currently may be legally exported to Canada and Mexico. Deregulation of RR alfalfa use for feed in Japan occurred in February 2006, but importers may nevertheless require imported alfalfa hay to be non-GE.

Table 1. Total production and exports of alfalfa and alfalfa mixtures, six western U.S. states (CA, ID, NV, OR, UT, WA) and U.S. total

	1997	1998	1999	2000	2001	2002	2003
Alfalfa production (metric tons)	17,585,823	17,868,807	17,678,337	17,362,701	17,475,169	18,852,902	18,478,311
Alfalfa exports (metric tons)	841,748	790,769	827,303	853,268	782,137	782,137	839,532

	1997	1998	1999	2000	2001	2002	2003
Percentage of alfalfa production exported (six states total)	4.79	4.43	4.68	4.91	4.48	4.15	4.54
Percentage of U.S. alfalfa exported	1.06	0.96	0.98	1.06	0.97	1.06	1.10

Sources: Production data is from NASS 2005; export data is from the Journal of Commerce 2004 and includes compressed hay and cubes.

How much of the alfalfa market will be sensitive to GE traits?

When considering alfalfa markets, it is important to note that alfalfa growers do not receive government subsidies, that alfalfa marketing is highly decentralized, and that its markets follow free-market conditions to a greater degree than do most agricultural commodities. Although markets reward genuinely higher-quality hay according to laboratory tests (Putnam 2004a), highly subjective and nonscientific factors frequently enter into sales. This is pertinent to the GE question. Perceptions are often more powerful than scientific arguments for buyers, and subjective factors related to forage quality and feed safety must be considered by producers who wish to sell to those markets.

It is clear from the above discussion and other analyses (Putnam 2004b) that the vast majority of alfalfa is grown for uses or markets that are not highly sensitive to the presence of GE traits. The primary markets sensitive to the GE trait in alfalfa are export markets, organic markets, and some hay grown for horses. This is likely to be less than 5 percent, and probably less than 3 percent, of annual U.S. production, but the degree of sensitivity will become more apparent as the trait is tested by growers. These sensitive markets require that GE traits successfully coexist with non-GE traits on farms and in regions where those markets are important. The presence of GE alfalfa may actually increase the demand for non-GE alfalfa or organic alfalfa, sharpening the need for product identity, trait stewardship, and coexistence on farms and in markets.

What practices can be used to allow GE and non-GE alfalfa varieties to coexist?

Coexistence between GE and non-GE alfalfa depends on understanding the biology of alfalfa production and techniques to assure market identity. The stewardship of purity of non-GE and GE traits for hay production within a region or farm depends on a range of practices, beginning with seed selection, and including the following eight points.

1. ***Select certified varieties for seed purity and quality***

The first step in stewardship of GE and non-GE alfalfa hay is the choice of high-quality seed. Only certified seed should be grown. This is likely to be the most crucial step in assuring purity in a hay product for growers selling into sensitive markets. While it is very difficult for traits (genes) to pass from one alfalfa hay field to another, some adventitious presence (AP) may occur during seed production if care is not taken to prevent it. Adventitious presence is a low level of presence of a trait (such as a GE trait) in a variety meant to be free of that trait. Crop inspection and certification services in each state have standards and recommendations to assure seed purity, which include variety identity, seed quality, and lack of contamination with weeds or foreign matter (Mueller 2004). However, testing and reporting of AP in certified seed is not required; growers who are concerned about AP of a GE trait in alfalfa seed should ask the seed company about it, and ask that it be tested or test the seed themselves. Strip tests are available for seed that can be used by growers interested in maintaining non-GE alfalfa.

2. ***Understand the potential for gene flow***

Alfalfa is cross-pollinated, requiring insect pollinators, usually honey bees (*Apis mellifera)* or leafcutter bees *(Megachile rotundata* F.) to transfer pollen from one plant to another for seed production. Cross-pollination is not required for forage production. The potential for gene flow in alfalfa grown for hay is not the same as that for alfalfa grown for seed crops due to very different production methods. The upper limits for gene flow in hay fields, however, can be estimated by looking at what happens during seed production (Mueller 2004; Rincker et al. 1988). Studies in seed fields in Idaho using leafcutter bees as pollinators showed gene flow from an RR alfalfa seed crop to a non-GE crop to be about 1.5% at 500 feet (152 m), less than 0.5% at 900 feet (274 m), and zero at 2,000 feet (610 m) (Fitzpatrick et al. 2002). Honey bees generally have longer flights than leafcutter bees; a study in California using honey bees as pollinators showed gene flow to be 1.5% at 900 feet (274 m) and below 1% at 2,500 feet (0.8 km), but sporadic gene flow (< 0.03%) could be detected up to 2.5 miles (4 km) away (Teuber et al. 2004; Van Deynze et al. 2004). These estimates were obtained under conditions that maximize pollination and seed production, conditions that are unusual in alfalfa hay fields.

3. ***Understand the limits of alfalfa gene flow from one hay field to a neighboring hay field***

Although gene transfer from one alfalfa hay field to another is theoretically possible, a range of environmental barriers make gene movement very unlikely. For AP to occur in a hay field from a neighboring GE hay field, flowering must be simultaneous between fields (A and D, fig. 1);

pollinators must be present (B); they must move significantly between fields (C); the pollen must accomplish fertilization by tripping flowers and fertilizing the ovule of the flower (E); those fertile embryos must mature into seeds (F); those seeds must be retained in the field, fall to the ground, and germinate (G); and those germinating plants must survive the competition of existing alfalfa plants and contribute significantly to the dry matter yield of the subsequent hay crop (H). The vast majority of alfalfa fields are harvested with only a small amount of flowering (0 to 25%) and zero viable seed production. Most hay harvested for the dairy market in California is harvested in the prebloom (bud) stage for high quality. The whole crop is usually removed during harvesting. A long history of failure to intentionally overseed alfalfa into existing alfalfa fields (Canevari et al. 2000) provides evidence that even in the rare case that seed were produced and left in the field, it would not be likely to germinate, grow, and compete with the existing crop and contribute significant biomass to the subsequent hay crop. Although the probability of each of these steps is not fully known, if one starts with an upper limit of 1.5% AP in seed fields at 900 feet (274 m) and applies the estimated probabilities above, the likelihood of AP occurring between hay fields becomes infinitely small, likely to be far less than 0.001% of field biomass even under high estimates of each of these probabilities. The combination of frequent harvests, lack of significant flowering, lack of significant seed production, and the highly competitive and allelopathic nature of alfalfa that prevents ready germination of alfalfa seeds in existing fields should prevent most if not all gene transfer. However, growers should be aware that conditions that increase the potential for

AP include excess flowering, high levels of pollinator activity, and conditions such as excess heat and late harvests where seed is allowed to mature, and should take steps to prevent or avoid these conditions.

[Figure 1 omitted.]

4. ***Control feral alfalfa near hay fields***

Cultivated alfalfa is not known to cross with any wild non-alfalfa *Medicago* species plants or with any weed present in the United States. It will, however, cross with feral, or wild, alfalfa *(Medicago sativa* L.) plants. Feral alfalfa is alfalfa that grows along ditch banks or roadsides that remains unharvested. It can originate from highway plantings, spilled seed, small amounts of seed from hay, or movement by birds. Since feral alfalfa is more likely to flower and set seed than alfalfa grown for hay, it may act as a bridge for pollinators between distant fields. Controlling feral alfalfa is a prudent measure to prevent movement of genes between hay fields.

5. ***Identify non-GE alfalfa hay***

The coexistence of GE and non-GE alfalfa requires a high level of awareness of crop identity for products destined for sensitive markets. This may require identification of hay lots to assure that hay lots are not mixed, a process currently practiced on commercial hay farms by growers who mark, test, and sell lots by field and farm. Organic growers already have a process by which they identify and document organic hay, so no greater paperwork burden would be generally required to deal with this situation. A "lot" for forage quality testing purposes is defined as a stack from the same field, same cutting, weighing less than 200 tons (1,814 metric tons), with identification as to farm and field and cutting (Putnam 2002). This definition should also be

used for GE as well as non-GE hay product identification.

6. ***Prevent mixing of hay lots***

Growers wishing to sell into sensitive markets must take steps to prevent the mixing of haystacks, to maintain identity, and to assure customers of that identity throughout harvesting, storage, and transport. For example, growers may use specific colors of twine to assist farm managers, farmworkers, truckers, buyers, and sellers to maintain product identity during marketing and shipping. Export and organic markets already require paperwork that identifies the lot, seller, and origin of hay, so a GE or non-GE label may be relatively simple for these marketers.

7. ***Test for GE traits in hay***

Testing procedures and test strips (available from, for example, EnviroLogix, http://www.envirlogix.com/, and Strategic Diagnostics, http://www.sdix.com/) for market identification of GE traits are routinely used for corn, soybean, and other crops, and they are now available for RR alfalfa hay. There are leaf tests for field-side analysis of fresh plant samples, mobile cored sample hay kits for testing haystacks, and commercial laboratory tests for testing of routine cored and ground hay samples. Early tests have shown that test strips detect RR hay successfully at levels of 5% or 100% and show lack of response at 0% (fig. 2). Using these tests should enable growers to confirm the absence of GE traits in their hays destined for sensitive markets and provide assurances to buyers as to the stewardship of non-GE hay.

[Figure 2 omitted.]

8. *Understand tolerances*

Given that the tolerance (requirements for labeling) for GE traits in food crops in Japan is 5% and 0.9% in Europe, the very small probabilities described above for AP in hay (animal feed) crops should not normally present difficulties for buyers of non-GE hay. For organic producers, the very small potential for AP should not ordinarily present significant worries for their markets, akin in many respects to the probability of influence of any nonorganic practice (such as spraying or fertilizing) from nonorganic fields that are grown in proximity to organic fields. The probability of gene flow and adventitious presence is quite low. Growers should be aware of conditions that facilitate gene movement (abundant flowering, seed production in hay crops) and should take steps to limit the potential for gene flow for markets sensitive to the presence of GE traits.

CONCLUSIONS

Roundup Ready alfalfa was deregulated in June 2005, the first GE trait to be commercialized in alfalfa. A large majority of alfalfa growers will choose or reject this technology based on need and economic factors, since the vast majority of their markets are insensitive to the presence or absence of GE alfalfa varieties. However, some growers (estimated to be 3 to 5%) producing for organic uses or export to countries or buyers concerned about GE crops must grow non-GE varieties and assure customers of the stewardship of the non-GE status of their crop. Simple methods to assure coexistence without disruption of these markets should be effective under most conditions. The probabilities of gene transfer are estimated to be very low between alfalfa hay fields. The most important

steps to assure hay trait purity are selecting non-GE varieties using certified seed from reputable companies, testing this seed for adventitious presence before planting, and maintaining product identity. Prudent steps to prevent excess flowering or seed production during hay production will be beneficial to maintain coexistence of GE and non-GE alfalfa. Steps to identify lots and maintain product identity are already in place for most commercial hay growers for organic and export markets, but these steps become more important to maintain non-GE identity for sensitive markets. Analytical test strips provide further assurance to customers of product identity. An understanding of biological and commercial factors affecting trait conservation is important in maintaining successful coexistence between GE and non-GE alfalfa production systems.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS INC., et al., Plaintiffs,	)	Case No. C-06-1075 (CRB) (EDL)
vs.	)	**JUDGMENT**
MIKE JOHANNS, et al., Defendants,	)	**IN A CIVIL CASE**

[Proposed Judgment filed by Federal Defendants]

IT IS ORDERED AND ADJUDGED that, pursuant to the Memorandum and Order filed 13 February 2007 ("Order"), judgment is entered (1) in favor of plaintiffs' as to their First Claim and Second Claim and (2) in favor of defendants ("APHIS") as to plaintiffs' Third Claim, Fourth Claim, Fifth Claim, and Sixth Claim. The Court dismisses plaintiffs' Fourth Claim with prejudice; it dismisses plaintiffs' Third Claim, Fifth Claim, and Sixth Claim without prejudice.

Pursuant to the Order, defendants' 14 June 2005 Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate is hereby vacated and replaced by the terms of this judgment. Before making any further decision whether to approve nonregulated status, APHIS shall prepare an environmental impact statement ("EIS"). APHIS shall complete such EIS within two years after the date of entry of the Judgment. Until then, the growing and use of the J101 and J163 alfalfa challenged here ("challenged alfalfa" or "RRA") shall be subject to the following provisions:

First, APHIS adopted its nonregulated status decision on 14 June 2005; plaintiffs filed their Complaint on 16 February 2006. In the interim, and during the pendency of this lawsuit, farmers and others planted the challenged alfalfa for both forage production and seed production on properties not specified in the administrative record. Therefore, for challenged alfalfa introduced before the date of entry of this Judgment, this Court cannot practically order a remedy or otherwise restrict this alfalfa. The Judgment does not require any person who planted the challenged alfalfa between 14 June 2005 and the date of entry of this Judgment to remove or destroy the plants or seeds, and it does not restrict the use of the harvested forage or movement of harvested seed by seed producers to Monsanto or Forage Genetics, Inc. Further, nothing in this Judgment requires regulation by APHIS of any challenged alfalfa planted between 14 June 2005 and the date of this judgment.

Second, the challenged alfalfa may be introduced after the date of entry of this Judgment, but only subject to the following conditions:

I. APHIS will require isolation distances between RRA and alfalfa seed production fields to mitigate any potential pollen mediated gene flow.

A. APHIS will require that pollinators shall not be added to RRA fields grown only for hay production.

B. APHIS will require that growers of RRA identify and keep records of all alfalfa crops being grown within 500 feet of their fields.

C. APHIS will require the following specific isolation distances:

1. When RRA is grown for hay production, APHIS will require that RRA be planted 165 feet from any alfalfa fields used for certified seed production.
2. When RRA is grown for seed production, APHIS will require that RRA be planted using the following isolation distances:
   a. 1500 feet from any alfalfa fields used for seed production, when leaf cutter bees are used to pollinate RRA; and
   b. 3 miles from any alfalfa fields used for seed production, when honey bees are used to pollinate RRA.

II. APHIS will require specific harvesting conditions for RRA fields to minimize gene flow in areas where growers are producing common alfalfa seed.

A. APHIS will require that all RRA hay fields be harvested prior to seed set

B. APHIS will require that RRA fields located within 165 feet of any alfalfa field grown for common seed production shall be harvested pre-bloom.

C. APHIS will require that RRA fields located between 165 and 500 feet from any alfalfa field grown for seed production shall be harvested at or before 10% bloom.

III. APHIS will require that farm equipment used in RRA production be properly cleaned after use.

A. APHIS will require that cleaning procedures for planters, harvesters, tractors and tillage equipment be submitted to and approved by APHIS prior to implementation.

B. APHIS will require that cleaning procedures be designed to minimize the risk of RRA seed and hay movement from the authorized production site.

C. APHIS will require that all equipment be cleaned in accordance with the approved procedures before it leaves the farm on which it came in contact with RRA.

IV. APHIS will require that RRA be handled and clearly identified to minimize commingling after harvest. APHIS will require that, immediately after harvest, growers or seed producers store RRA seed in specifically designated and clearly labeled containers until seed is transferred to Forage Genetics, Inc.

V. APHIS will require that RRA shall not be used for livestock grazing purposes or in a mixed grass pasture in order to ensure that the harvesting and management requirements specified in this judgment are met.

VI. APHIS will require that all RRA seed producers and hay growers must be under contract with Monsanto or Forage Genetics, Inc. These contracts must require compliance with the five preceding conditions, and these conditions must be followed for the entire life of the RRA stand.

APHIS will issue an order to Monsanto and Forage Genetics, Inc. imposing the foregoing conditions for any introductions of RRA after the entry of this judgment. APHIS will publish in the *Federal Register*, as soon as practicable, a notice advising the public of the terms of this judgment.

_____

Charles R. Breyer
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE CHARLES R. BREYER

GEERTSON SEED FARMS, et al.,	)	
Plaintiffs,	)	
vs.	)	No. C-06-01075 CRB
MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al.,	)	
Defendants,	)	

San Francisco, California
Thursday, March 8, 2007

Reporter's Transcript Of Proceedings

* * *

[28]

THE COURT: It would be impractical?

MR. McCASLIN: It would be impractical. And, also, there is nil opportunity for pollen flow from hay to hay.

I think to focus—so the way we've looked at it is how do we mitigate—what can we do to mitigate the potential for gene flow where there is seed production?

Which is, I think, at least in our mind, is kind of where we focused all of our attention.

THE COURT: And that can be done—

MR. McCASLIN: Combination of enforced harvest, at a certain stage, and when the—when the hay production is within a certain distance of seed production.

And what that distance—what that distance needs to be and what stage you need to harvest, I think there's a lot of scientific studies to actually make a science-based decision in terms of what that should be.

THE COURT: Is this in your proposed—did you submit—I haven't read it yet, so I don't know.

MR. McCASLIN: Actually, the one that presents this in the most detail is Hoffman's second declaration. So it's—you'll see it in our papers, but he actually does a pretty **[29]** exhaustive analysis of kind of the scientific data behind what their recommendation is. And he cites all of the relevant scientific studies.

THE COURT: I'm particularly interested in the—I understand that his reasons are there. But I'm particularly interested in reviewing the language of the relief, because at the end of the day, that's about where I—that's what I have to do.

Obviously, I'll hear from the plaintiffs on these issues, but you're telling me to go look at that. And maybe I have to ask counsel, is that where I'm going to find this delineation as to what I can do or what I should do, and what I shouldn't do?

MR. BROWN: Your Honor, if this would be an appropriate time to turn to that and to the proposed order that the intervenors have brought forward—

THE COURT: Do you have an extra copy of it?

MR. BROWN: I'm sure we do. Although, I need to find one without notes, Your Honor. Just a moment.

THE COURT: All right.

MR. ROSTOV: Your Honor.

THE COURT: Yes.

MR. ROSTOV: Do I have the opportunity to ask Mr. McCaslin a couple of questions?

THE COURT: Sure. Well, why don't we take a moment. **[30]** Or why don't you come on up, and if you want to comment on what he has just told me, you can do that. I don't know that we want to turn this into an examination/cross examination.

MR. PAGE: Your Honor, may the government respond after plaintiff questions?

THE COURT: Sure. Everybody can respond.

MR. ROSTOV: Maybe it's not questions, Your Honor.

THE COURT: Sorry?

MR. ROSTOV: I could have questions or I could point to a couple of places in his declaration.

THE COURT: However you want to proceed. What are your concerns about what he just said?

* * *

[36]

THE COURT: Maybe what I have to do is listen to the other side make their case that it's going to cause a severe economic hardship by telling them—let's say I propose telling the government to tell the farmers don't plant anything. Don't—I don't mean don't plant anything. Don't plant any of the seed. No, no, no, don't plant it. It's planted, okay. Don't plant it if it's not. A nice simple **[37]** bright line.

It's easy, in my point of view. I don't say you have to be greater than 1.6 miles, you have to be away from the bees, you have to be dah dah dah. That's the farm business. I'm not even in it. I don't know how you even start to enforce it. Drives everybody nuts. More government regulations. You know, they operate at their peril. It complicates it.

It does complicate it to try to fine-tune a particular remedy. So the simpler the remedy, the more attractive it is from the Court's point of view, because it appears to me enforcement is easier. Understanding it is easier, and it may be, while a blunt instrument, it may actually, for the short term, achieve its result, achieve its purpose, even maybe it overachieves it. Maybe in the shortrun it overachieves it. Maybe a lot of it is not necessary. I don't know.

I don't know, for example, whether these genetically engineered seeds, whether you can keep them for a year, or what their shelf life is. I don't know any of that. I'm not in the seed business. I have no idea.

Is it like, you know, a gallon of milk, if you don't do something with the milk or the eggs they turn, and so you have something that's—you know, that immediately would need to be destroyed, or is it not? I don't know that.

Maybe I have to ask them to demonstrate to me why—

* * *

[44]

MR. PAGE: And, Your Honor, we believe that this second declaration and the refined and broadened proposed judgment that Dr. Hoffman submitted as attachment B to his second declaration answers all your questions.

Because it does not only require the industry to adopt harvesting protocols either before bloom or before a certain percentage of bloom, such as 10 percent—and you will see the distinctions—but it also adopts isolation distances that are specific to the type of bee—

THE COURT: I am not going to get into the isolation distances.

MR. PAGE: Okay.

THE COURT: What I need to know is, I guess from the plaintiffs, is, what's wrong with the proposal that says just what I said?

And I also need to know from FGI—is it FGI? They abbreviated it. I need to know, what happens if a farmer has these genetic seeds, and by virtue of these circumstances can't plant them? What does FGI do? Does it accept the seeds back? Does it offer a rebate?

That's all a matter of their contracts, I suppose, or licenses, or whatever. I don't know how that works.

Do they give them a substitute seed? What could they do? What do they do? What do they do?

* * *

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS Inc., *et al.*, Plaintiffs, v. MIKE JOHANNS, *et al.*, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE, Intervenor-Defendants.	Case No. C 06-1075 CRB **DECLARATION OF ANNETTE M. KIRK IN SUPPORT OF MONSANTO COMPANY'S MEMORANDUM ON PROPOSED PERMANENT** Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

DECLARATION OF ANNETTE M. KIRK, IN SUPPORT OF MONSANTO COMPANY'S RESPONSE ON PERMANENT INJUNCTIVE RELIEF

I, Annette M. Kirk, declare as follows:

1. I am the Lead for the Federal Chemical Regulatory Affairs Team for the Monsanto Company ("Monsanto") Department of U.S. Chemical Regulatory Affairs, a position I have held since 2006.

2. I first joined Monsanto in 1980. I have twenty-seven years of experience with them and have held numerous positions of increasing responsibility in Environmental Health, Product Safety Assessment and Chemical Regulatory Affairs to my present position with the company. I have designed study protocols, and participated in the conduct of and data analyses for studies designed to identify hazards and to aid in the assessment of risk to human health and the environment, including cellular assays and other studies evaluating oral toxicity, dermal toxicity, inhalation toxicity, eye and skin irritation and dermal sensitization for various Monsanto products. I have had regulatory oversight and coordination responsibility for certain glyphosate end-use product and residue studies since 1997, or for about 10 years. As a result, I am familiar with the chemical and environmental profile of glyphosate, as well as its physical properties and characteristics.

3. From 1997 through 2005, I was a Registration Manager in U.S. Chemical Regulatory Affairs. In this capacity, I was directly responsible for the development and implementation of a regulatory strategy to gain certain U.S. approvals for the use of glyphosate in Roundup Ready®[1] crops, including Roundup Ready alfalfa. In particular, as part of my responsibilities for Roundup Ready alfalfa, I ensured that the required studies were carried out to obtain approval from the U.S. Environmental Protection Agency ("EPA"), which I obtained. This included drafting the analysis necessary to obtain "reduced risk"

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1 ®Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

status for the use of glyphosate in Roundup Ready alfalfa, from EPA, as discussed in more detail below.

4. I have been a member of Monsanto's cross-functional team for Roundup Ready alfalfa since its origination in 1999, eight years ago. The purpose of this team was to develop timelines and strategies for the development, approvals, and commercialization of Roundup Ready alfalfa. The team assessed the types of data that would be necessary to obtain requisite approvals and to evaluate and satisfactorily demonstrate its safety as animal feed as well as to humans and the environment.

5. In my role on the team, I was responsible for coordinating glyphosate residue studies on Roundup Ready alfalfa, including study protocol design, and for submitting the final residue study report, proposed labeling (use instructions) and tolerance petition which would be necessary to obtain EPA tolerances for glyphosate and label approvals.

6. I have a Bachelor of Arts degree in biology (with a minor in chemistry), received from the University of Missouri, St. Louis, Missouri in 1983. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

7. I have personal knowledge of the matters referred to herein and if called upon to testify could and would testify truthfully thereto.

U.S. EPA APPROVALS

8. Glyphosate (the active ingredient in Roundup branded agricultural herbicides) was first registered and approved as an agricultural herbicide with the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in 1974. Glyphosate was reregistered by EPA in 1993, and the agency confirmed

its earlier conclusion that glyphosate-based herbicides used in accordance with label directions will "not pose unreasonable risks or adverse effects to humans or the environment." In making these findings, EPA reviewed over one hundred studies, including those required by the agency as outlined in 40 C.F.R. pt. 158, but not limited to studies on product chemistry, toxicological effects, environmental fate and ecological effects, such as effects on non-target terrestrial and aquatic species, crop metabolism (nature of the residue) and crop residue (magnitude of the residue). The use of a pesticide inconsistent with its label is a violation of FIFRA.

9. EPA has granted "reduced risk" status for the use of glyphosate in a number of Roundup Ready crops, including Roundup Ready alfalfa, to allow for expedited review of submitted data supporting these uses. Reduced risk status was granted based on the favorable mammalian and non-target species toxicity profile and environmental profile of glyphosate compared to other herbicides available for weed control in alfalfa. Glyphosate inhibits an enzyme that is essential to plant growth; this enzyme is not found in humans or other animals, contributing to the very low risk to human health from the use of glyphosate according to label directions.[2]

10. Glyphosate also has favorable environmental characteristics, including that it binds tightly to most soils, making it unlikely to move to groundwater, as compared to several other herbicides used in alfalfa production, and it degrades over time in soil and in

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[2] Franz, J.D., M.K Mao, J.A. Sikorski. 1997. Glyphosate: A Unique Global Herbicide. ACS Monograph No. 189. American Chemical Society, Washington, D.C.

water in the environment making it less likely to reach surface water through run-off from soil.[3] Importantly, as I will discuss in more detail below, glyphosate has been shown to have favorable environmental characteristics compared to other herbicides.[4]

11. Monsanto has continued to study glyphosate and its safety and effectiveness for the last thirty-three years. Glyphosate is approved for use in at least eighty-five crops and is approved for use as an in-crop application on Roundup Ready crops, including Roundup Ready alfalfa. The first in-crop application of glyphosate on a Roundup Ready crop was registered and approved by EPA in 1996. This newer application of glyphosate permits growers to use glyphosate-based products for weed control after the crop has emerged, without damaging the crop.

12. Because an herbicide may only be marketed and sold for use in strict accordance with its label, prior to selling or distributing a glyphosate-based herbicide product for a new use, Monsanto must register the new use and obtain EPA labeling approval. As mandated by FIFRA, EPA must review studies to determine that the new use does not pose unreasonable risk to human health or the environment. Additionally, under the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 321, *et seq.*, EPA must also determine that

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[3] Giesy, J.P., Dobson, S., K.R. Solomon. Ecotoxicological risk assessment for Roundup herbicide. Rev. Environ. Contam. Toxicol. 167: 35 – 120 (2000).

[4] Nelson, G.C. and D.S. Bullock. 2003. Environmental effects of glyphosate resistant soybeans in the United States. The Economic and Environmental Impacts of Agbiotech: A Global Perspective. Kalaizandonakes, N. (ed.). Kluwer Academic/Plenum Publishers, New York.

any herbicide residues in or on food or feed will be safe before it may approved the new use. In making this determination, EPA establishes tolerances, which are the maximum levels of an herbicide active ingredient allowed to remain in or on treated food or feed commodities. EPA's tolerance determinations are based on crop residue data for that herbicide generated using maximum applications rates and crop growth stage timings intended for the proposed use. When a Roundup Ready crop is developed, with its corresponding new in-crop use of a Roundup agricultural herbicide, EPA reviews data submitted to support the new use and determines whether to amend the pesticide registration and approve new labeling.

13. Monsanto conducted extensive testing to support the use of glyphosate on Roundup Ready alfalfa consistent with EPA regulatory requirements, including field residue trials conducted over about a one and a half year period during 2000 – 2001. These studies are known as Magnitude of the Residue studies, and are typically conducted using application rates and crop growth stage timings for the herbicide that will provide maximum flexibility and optimum weed control in the cropping system. The residue study included planting locations that represented the major alfalfa growing regions in the U.S. and thus included thirteen locations across the U.S., both spring and fall plantings, for forage and hay production and three locations for seed production.

14. Maximum average glyphosate residue levels found were 86.6 ppm in alfalfa forage, 262 ppm in alfalfa hay and 0.37 ppm in alfalfa seed. These results demonstrate that residue levels in alfalfa forage and alfalfa hay from this new proposed use for Roundup

Ready alfalfa were well within the then existing tolerances of 175 and 400 ppm for these commodities, respectively, and within the pending proposed tolerance at the time of 400 ppm for Animal Feed, Non-grass, Group. *See* 40 C.F.R. § 180.364.

15. In 2005, based on the Roundup Ready alfalfa residue study discussed above, EPA established a tolerance for residues of glyphosate in or on alfalfa seed at 0.5 parts per million (ppm). In issuing the tolerances, the EPA concluded that there was "reasonable certainty that no harm would result to the general population, and to infants and children from *aggregate exposure* to glyphosate residues."[5] *See also* 40 C.F.R. § 180.364 (emphasis added).

16. Monsanto also petitioned EPA for and received "reduced risk" status for glyphosate use "over the top" of Roundup Ready alfalfa. This "over the top" use would permit growers to use glyphosate for weed control after the crop has emerged or to apply a Roundup brand agricultural herbicide "over the top" of the crop. I prepared and submitted the petition for "reduced risk" to EPA, which compared glyphosate to the top alternative herbicides available for weed control in conventional non-glyphosate tolerant alfalfa.

17. EPA's approval of the labeling for the use of glyphosate in Roundup Ready alfalfa made it possible for the reductions in risk and the benefits of the system (crop + herbicide) supported in Monsanto's reduced risk petition to be realized in a practical sense. The reduced risk petition for glyphosate use in Roundup Ready alfalfa demonstrated that the use of Roundup

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[5] 70 Fed. Reg. 7861 (Feb. 16, 2005).

UltraMAX herbicide in this system offered the opportunity to:

(i) reduce the potential risk of adverse effects to applicators of herbicide products as compared to available alternative herbicides;

(ii) reduce the potential risk to non-target organisms due to the relatively lower toxicity of glyphosate to birds, bees, aquatic organisms and other wildlife as compared to some of the available alternative herbicides; and

(iii) to reduce the potential for contamination of the ground and surface water because glyphosate binds tightly to most soils, is degraded over time by soil microbes, and therefore is not likely to leach through soil to reach groundwater or reach surface water through run-off from soil. Glyphosate also dissipates from surface water more rapidly than most other herbicides, and it is one of the few herbicides that have been approved for the control of aquatic vegetation by the EPA.

18. Unlike some other herbicides, glyphosate that may be present in the environment is not significantly absorbed and does not significantly accumulate in the tissue of animals or fish, and non-target species are at minimal risk of effects from its use according to label directions. Comprehensive toxicological studies in animals have demonstrated that glyphosate when administered by oral, dermal or inhalation routes has very little acute toxicity.[6] Toxicology studies

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[6] U.S. EPA, 1993; Williams, G.M., R. Kroes, and I.C. Munro. 2000. Safety Evaluation and Risk Assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. Reg. Toxicol. Pharmacol. 31(2): 117 – 165; European Commission.

specifically on wildlife animals, including birds, fish, insects and other invertebrates, have further confirmed glyphosate has very low toxicity to wildlife and that expected exposure from approved uses of glyphosate would pose no unreasonable risk to wildlife.[7]

19. Under present and expected conditions of use, glyphosate-based herbicides, when used according to label directions do not pose a health risk to humans. Toxicology studies have confirmed that glyphosate does not cause cancer, birth defects, mutagenic effects, nervous system effects or reproductive problems. The EPA has concluded that glyphosate has low acute toxicity and no other toxicological concerns and therefore will not pose unreasonable risks or adverse effects to humans.[8]

20. Reduced risk status was granted based on EPA's independent review of Monsanto's assessment of the hazard profile from publicly available data and the potential for reductions in risk to human health, non-target organisms and contamination of ground and surface water from the use of a glyphosate-based product as compared to other herbicides available for weed control in alfalfa production. EPA had previously

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Report for the Active Substance Glyphosate, Directive 6511/VI/99, January 21, 2002; WHO/FAO, Pesticides residues in food. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Enviornment and WHO Core Assessment Group on Pesticides Residues. Rome, Italy, September 20 – 29, 2004.

[7] *Id.*

[8] U.S. Environmental Protection Agency. (1993) Reregistration Eligibility Decision (RED): Glyphosate. EAP-738-F-93_011, September 1993, Washington, D.C. http://www.epa.gov/oppsrrd1/REDs/old_reds/glyphosate.pdf.

granted reduced risk status to allow for expedited review of Monsanto's submitted data supporting approval for the use of glyphosate in Roundup Ready canola, corn, sugar beets, and wheat. A true and correct copy of the EPA letter granting reduced risk status for expedited review of submitted data supporting the use of glyphosate in Roundup Ready alfalfa is attached as Exhibit B to this declaration.

21. EPA has stated that it coordinates the review and approval of new labeling for herbicide tolerant crops with the other U.S. regulatory agencies. Pursuant to a 2001 Memorandum of Understanding ("MOU") between the U.S. Department of Agriculture ("USDA") and the EPA, the USDA and EPA agreed to coordinate their approval processes for herbicide tolerance crops. According to the MOU, the agencies established an interagency working group to ensure that the concerns of each individual agency are addressed relative to the new herbicide crop prior to any agency granting its approval. A true and correct copy of the MOU is attached as Exhibit C to this declaration.

22. Following EPA's review of extensive data submitted by Monsanto, EPA amended the registration and labeling of Roundup UltraMax® herbicide (EPA Reg. No. 524-512) to allow for the application of glyphosate for weed control in Roundup Ready alfalfa (in both forage and seed production). EPA approved the label for use of glyphosate on Roundup Ready alfalfa for production of seed in August 2004, and EPA approved the label for use of glyphosate on Roundup Ready alfalfa for forage and hay production in June 2005. True and correct copies of the EPA approved labels are attached as Exhibits D and E to this declaration.

* * *

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 23rd day of March, 2007 in Siesta Key, Sarasota, Florida.

/S/
Annette M. Kirk

Attorney Signature Attestation

I, Holly J. Tate, counsel for Monsanto Company, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this efiled document.

/S/
Holly J. Tate

[EXHIBIT B]

[EPA logo omitted]

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, DC 20460

Sep -9 2002

[Fax transmittal information omitted]

Annette Kirk
Monsanto Company
600 13th Street, NW, Suite 660
Washington, DC 20005

Subject: Reduced Risk Status for Glyphosate for a New Use on Glyphosate-Tolerant Alfalfa

Dear Ms. Kirk,

On July 23, 2002 the Reduced Risk Committee granted reduced risk to your company's requests for a new use on glyphosate-tolerant alfalfa for your registered Roundup brand herbicides. Glyphosate will control a broad spectrum of annual and perennial weed species, and has favorable human health, ecological, and environmental fate profiles when compared to alternative herbicides in alfalfa.

The reduced risk status of any chemical is an initial assessment. Should information warrant, the Agency may re-evaluate and possibly revoke your submission's reduced risk status. Also, should the Agency determine at any time that the data base for your product is unacceptable or incomplete, the Agency may

stop the expedited process for the chemical until adequate data are submitted.

As a result of the decision to designate this use as reduced risk, the Agency will begin working with its science divisions to schedule the data reviews and risk assessments needed for evaluating this submission. The Agency has a goal of completing these evaluations in an expeditious manner. Jim Tompkins, the EPA product manager for your product, will now handle all regulatory issues associated with this application. Jim can be reached at (703) 305-5697.

Thank you for your interest in reduced risk pesticides. If you have any questions regarding the reduced risk pesticide program please feel free to contact Steve Schaible at (703) 308-9362.

Sincerely Yours,
/s/ Rachel C. Holloman
Rachel Holloman, Chief
Registration Support Branch
Registration Division (7505C)

cc: Jim Tompkins

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al. Defendants and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **DECLARATION OF MIKE PHILLIPS REGARDING PERMANENT INJUNCTION** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I Mike Phillips, declare:

1. I am a farm manger and vice president of Nevada Nile Ranch located in Lovelock, Nevada. I previously provided a declaration in this action in support of the Motion to Intervene of John Grover, Daniel Mederos and Mark Watte, a copy of which is attached. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. We currently have 4,565 acres devoted to growing alfalfa for forage, 780 acres of which are

currently planted with RoundUp Ready alfalfa ("RRA"). Based on the results we have achieved with the RRA, our plan is to move all of our alfalfa forage into RRA. In our area, noxious weeds are a real problem that can affect both the value and marketability of our hay. Such noxious weeds include Russians Knapweed, Tall White Top, Morning Glory and Dodder. Using RRA eliminates the noxious weed problem. Not only does RoundUp eliminate the noxious weeds, it is significantly less expensive than the alternative chemicals like Raptor. While one application of RoundUp costs approximately $7.00 per acre, an application of the alternative herbicides can run $35 to $40 an acre. Moreover, RoundUp is much more effective in eliminating weeds than the alternative chemicals.

3. If the court's preliminary injunction order preventing more planting remains in effect, it will disrupt our current plans to plant another 950 acres of RRA this fall. If forced to plant conventional alfalfa on those acres, even if RRA is de-regulated again after that time, it will be eight to nine years before I can plant RRA on those acres. This is because an alfalfa stand lasts anywhere from five to seven years and once that stand is taken out, we plant grain for one to two years before those acres can rotate back into alfalfa. Thus, a court order preventing me from planting RRA this fall, even if of short duration. will negatively affect me and my operation for years to come. The economic effects of not being able to plant RRA will be loss of the greater yields, the greater price associated with the higher quality hay, and the increased expense associated with the herbicides that I will have to use to control weeds on any conventional alfalfa. Since selling

alfalfa is our primary business, these losses would be significant.

4. We also grow alfalfa seed. Of the 1,040 acres devoted to this crop, 750 acres are planted with RRA seed under contract with FGI. Our conventional seed is also grown under contract with FGI. Prior to the court's preliminary injunction order, we were planning on planting another 250 acres of RRA seed, however those plans are now on hold. If the court continues to prevent the planting of more RRA seed, the loss of income from these acres could be as much as $190,000. If the court issues an order that affects my ability to get paid for the 750 acres currently devoted to RRA seed, the potential losses (given that I have contracts to cover 2007 to 2009) could be as much as $2,500,000. Moreover, the acreage currently devoted to RRA seed, even if I were to tear it out, could not be rotated back to conventional alfalfa seed for three years. While I could plant grain on those acres, at best I would be marginally profitable and would more likely only break even.

5. Co-existence with organic producers of alfalfa should not be a problem in Nevada. Based on the Nevada Department of Agriculture List of Certified Organic Producers and Handlers, there are only nine growers of organic hay in the entire state and they are all in isolated areas that are far away from our operation.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct.

Executed this 21st day of March 2007 at Lovelock, Nevada.

/s/Mike Phillips
MIKE PHILLIPS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE. GENETICS, INC and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **DECLARATION OF PAUL RASGORSHEK REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor The Honorable Charles R. Breyer

I, Paul Rasgorshek, declare:

1. I farm 3,100 acres in Nampa, Idaho. I own 900 acres and lease 800 acres on which I grow row crops. I farm the other 1,400 acres under a contract with a dairyman and grow 650 acres of corn and 750 acres of conventional alfalfa for forage. I have been farming since 1981 and started growing alfalfa seed around 1990. My parents and grandparents were also farmers. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. Of the 750 acres of conventional alfalfa that are planted on our contract acreage, the plan is to replace 150 of those acres with RoundUp Ready alfalfa ("RRA") this fall. With RRA, we were hoping to achieve the benefits of being able to have a first cutting sooner and with a better yield. With conventional alfalfa, the herbicides used at the seedling stage of the stand are so harsh that they actually stunt the growth of the hay and as a result the entire stand is slower coming in. If the court's Preliminary Injunction Order is still in place by the fall, then we will have to plant more conventional alfalfa. Once we do that, even if RRA is de-regulated shortly thereafter, those acres will be tied up in conventional alfalfa for three to five years—years we will be denied the benefits of the cheaper costs and greater yields from RRA. So, a court order that prevents us from planting RRA this fall will affect us for many years to come.

3. On the 1,700 acres that I farm, we grow a number of crops including alfalfa seed, beans, beets, corn, hay, mint, seed peas, seed wheat, carrot seed, onion seed and flower seeds. All of our alfalfa seed is RRA seed that we grow under contract with Forage Genetics, Inc. ("FGI"). I first started growing RRA seed prior to de-regulation under authority of USDA. We planted 200 acres in the fall of 2004, 300 acres in the spring of 2005, 100 acres in the fall of 2005 and 100 acres in the fall or 2006 (we also tore out 40 acres of RRA seed that year as well) for a total net RRA seed acreage of 660 acres.

4. Before I planted any RRA seed, I met with representatives of FGI who explained all of the practices and procedures that I would be required to follow if I wanted to grow the crop. I signed the

Proprietary Seed Services Agreement for the Production of RRA Seed in which I agreed to follow the required stewardship practices. I was also provided with written materials detailing these practices. I also signed the Monsanto Technology/Stewardship Agreement and was provided with a copy of the Monsanto Technology Use Guide ("TUG"). I understand that the primary purpose for the stewardship practices was to minimize the potential for gene flow from our RRA seed operations to conventional alfalfa seed fields.

5. Since planting RRA seed, I have always followed the required stewardship practices in order to isolate RRA seed. The folks from FGI are often at my farm, particularly during the planting and harvesting seasons, to make sure the stewardship practices are followed. In addition, our operation is inspected by the Idaho Crop Improvement Association to make sure we are following the required practices to grow registered and certified seed.

6. As a seed grower of other types of seed, the concept of maintaining isolation distances to preserve varietal purity is nothing new. For example, there is required isolation distances that must be maintained between different types of onion seed fields. There is also isolation distances required for different varieties of carrot seeds. There are other examples as well. Like alfalfa seed, both onion seed and carrot seed are pollinated by bees—in those cases, honeybees. The isolation distances for these crops are imposed and enforced by the seed companies with whom the farmer contracts to grow the seed. Thus, maintaining isolation distances between seed crops that use bees as

pollinators to preserve varietal purity is an old and proven practice.

7. Our RRA seed crop is our bread and butter. It is our largest crop in terms of acreage and it is our most profitable crop. We gross approximately $1.1 million a year on our current acreage, which represents 40% of our gross revenue. We have approximately $2 million invested in equipment to farm our land, a significant percentage of which is used in the alfalfa seed operation. If I were to lose this crop and have to start over with conventional seed we would have several years to build back up to our current acreage with a rotation of the other crops and the contamination issue. There would be income loss for those years to build back the current acreage of alfalfa seed.

8. RRA is a tool that farmers need in order to be competitive and to survive. It results in a more valuable crop for the producer and the increased feed quality for the dairymen.

9. Weed resistance to all chemicals that are used over a period of dine is a fact of life. However, this can be dealt with, as it always has with other chemicals, by rotating the use of RoundUp with other herbicides in order to prevent the development of RoundUp resistant weeds. Given the value of RoundUp as a tool for the farmer, it is in every farmer's best interest to take steps to avoid developing RoundUp resistant weeds. In my opinion, most if not all farmers know how to do this.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct.

Executed this 21st day of March 2007 at Nampa, Idaho.

/s/ Paul A. Rasgorshek
PAUL RASGORSHEK

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **DECLARATION OF MARK WAGONER REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles Breyer

I, Mark Wagoner, declare:

1. I operate a 1500 acre farm in Touchet, Washington. I am a graduate of Washington State University with a degree in Agricultural Economics and have been farming for 32 years. I am the current president of the National Alfalfa and Forage Alliance, an alfalfa industry group. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. I currently have 1,100 acres of alfalfa seed that I am growing under contracts with five different

companies, including Forage Genetics, Inc. ("FGI"). 515 of my seed acres are under contract with FGI. I grow many different varieties of seed for FGI, but I do not grow RoundUp Ready alfalfa ("RRA") seed.

3. Although I do not grow RRA or RRA seed, Roundup is an important tool in my operation for dealing with weeds. Because Roundup is an important tool for me, the development of Roundup Ready resistant weeds would certainly not be in my best interest. It is well known that weeds will develop resistance to any chemical that is used repeatedly over a prolonged period of time. It is also well known that the way to avoid weeds developing resistance to any particular chemical is to rotate the chemicals used for weed control. In my case, if I use Roundup one year, the second year I may use alternative chemicals such as Velpar or Prowl. There is nothing complicated about this concept and I would be surprised if there are many farmers out there who don't know about it.

4. As a seed grower of many different varieties of alfalfa seed, I am well aware of the practice of maintaining isolation distances in order to maintain varietal purity. Isolation distances have been employed successfully in seed farming for decades. By maintaining proper isolation distances and following basic stewardship practices, the seed I grow is certified as meeting the standards set by the seed certifying agencies.

5. I see no reason why maintaining sufficient isolation distances will not adequately protect organic alfalfa from being contaminated by RRA. If isolation has been able to protect and preserve all of the other varieties of alfalfa seed that are out there, I can think of no reason why those same practices will not be

effective to preserve essential purity of organic alfalfa—there is simply nothing different about it.

6. In our area, I am not aware of anyone who grows organic alfalfa seed. In fact, in Washington I would think growing organic alfalfa seed would be almost impossible because of the prevalence of lygus bugs, which you have to control with chemicals or your crop will be wiped out. From my experience, you cannot grow alfalfa seed in this part of Washington without chemicals.

7. This does not mean, however, that you can't grow organic hay in Washington. In fact, I'm aware of an organic alfalfa farmer approximately five miles away from my farm. I have sold seed to farmers who intend to use it to grow organic alfalfa both in Washington and in the in Oregon. These organic alfalfa growers start with conventional seed and then follow the mandated organic process once it is planted. If they follow these required processes their hay can be certified as organic.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 21st day of March 2007 at Touchet, Washington.

/s/ Mark Wagoner
MARK WAGONER

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC., and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **DECLARATION OF TROY WATERS REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Troy Waters, declare:

1. I am an alfalfa seed grower in Fruita, Colorado and grow RoundUp Ready alfalfa ("RRA") seed under contract with Forage Genetics, Inc. ("FGI"). My family farms 1,032 acres in the Grand Valley of Mesa County, all of which are devoted to RRA seed. I previously provided a declaration in this case in support of the Motion to Intervene by John Grover, Daniel Mederos and Mark Watte, a copy of which is attached as Exhibit A. I have a personal knowledge of the matters set

forth herein and if necessary could competently testify thereto.

2. I am 40 years old and have lived and worked on a farm my entire life. Our farm is a family operation run by myself, my father Wayne and my brother-in-law Dusty Hatch. So, what happens on or to this farm affects the lives of three families.

3. We have seen a number of ups and downs over the years in the farming business, as well as the evolution of farming in our area. Although this wasn't always the case, the current reality is that 99% of what we produce must be shipped to other markets. Our economic viability depends on growing a crop that provides us with a return over the costs to ship it. It turns out that alfalfa seed is such a crop.

4. Our land is particularly suited for growing alfalfa seed. We had our first contract to grow alfalfa seed in 1994. In 1999, the company we had our seed contracts with went bankrupt, a situation we barely survived. In the next several years we were able to get a few small contracts to grow alfalfa seed with other companies including Pioneer, Dairyland and Cal-West, but we had to put the bulk of our acreage in wheat. Although we tried, it became clear during that time that we could not sustain our farming operation on wheat.

5. As members of the Northwest Alfalfa Seed Growing Association, we regularly attend the annual meetings and what they call the seed school where issues relating to the alfalfa seed growing business are discussed. It was at such meetings in or about 2001 - 2002 that we first heard that RRA was in development. Given the isolation of our farm from other alfalfa seed growing operations and FGI's need for isolation, we

felt our farm would be perfect to grow RRA. Given the success of other RoundUp Ready crops like corn and soybeans, we figured RRA would be successful if deregulated. Although finances were difficult, we made a decision at that time not to sell the farm and hold out for the opportunity to grow RRA seed. The only other alternative was to sell our farm to developers for housing.

6. In 2003 we had our first contract with FGI for 200 acres of conventional alfalfa seed. In 2004, however, FGI approached us to grow RRA seed as part of the testing process prior to deregulation. So we tore out the conventional alfalfa seed and planted 625 acres of RRA seed under authorization of USDA. In the summer of 2005 RRA was in fact de-regulated. In reliance on deregulation we invested heavily in the crop and in fact, felt it was safe to devote our entire operation to growing RRA.

7. I estimate that we invested $500,000 in equipment necessary to raise and harvest RRA seed, including a $200,000 spray rig and a $130,000 combine. We have also made significant investments in bees as pollinators (to achieve sufficient pollinization we need 50,000 bees per acre). For example, we have invested $50,000 in a bee incubator and additional amounts on bee blocks and other equipment. This is all equipment that we purchased with the expectation of using it to grow RRA seed for many years to come.

8. This fall we were planning on adding an additional 200-400 acres of RRA seed production, something we will be prevented from doing if the court's ban on further planting continues in effect. In addition to the potential loss of income from that acreage, we now have to deal with the uncertainty of

our farm's future, just when we thought our future was somewhat secure.

9. Our contracts with FGI for RRA have made it possible for our family farm to continue. The court's Preliminary Injunction Order threatens not only our investment in growing RRA seed and our contracts with FGI. but it could mean the end to a way of life for our entire family, which has always been in farming. If we are not allowed to continue raising RRA seed we will be required to sell our farm to developers for housing and then find other jobs. Given that we've never done anything but farm, I have no idea what that would be.

10. Since we are completely isolated from any conventional or organic seed production—the closest conventional alfalfa seed operation is more that 300 miles away in Delta, Utah—an order preventing us from further planting of RRA seed would be harsh on us, and would do nothing to address what I understand is the court's concern, i.e., to prevent contamination of conventional or organic seed operations.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 21 day of March 2007 at Fruita, Colorado.

/s/Troy Waters

TROY WATERS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, Inc., *et al.*, Plaintiffs, v. MIKE JOHANNS, *et al.*, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE, Intervenor-Defendants.	Case No. C 06-1075 CRB **SECOND DECLARATION OF PAULETTE PIERSON, PH.D. IN SUPPORT OF MONSANTO COMPANY'S MEMORANDUM ON PROPOSED PERMANENT INJUNCTION** Date: April 27, 2007 Time: 10:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

SECOND DECLARATION OF PAULETTE PIERSON, PH.D. IN SUPPORT OF MONSANTO COMPANY'S MEMORANDUM ON PROPOSED PERMANENT INJUNCTION

I, Paulette Pierson, Ph.D. declare as follows:

1. I am the Technology Development Manager for Roundup Ready®[1] Alfalfa and Roundup Ready Sugarbeet for the Monsanto Company ("Monsanto"), a position I have held since 2005. Monsanto is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality.

2. In my capacity as Technology Development Manager for Roundup Ready Alfalfa, I am responsible for overseeing the technical aspects of the development and commercialization of this product. My responsibilities in connection with Roundup Ready alfalfa have included overseeing the technical aspects of the full commercial launch of Roundup Ready alfalfa in February 2006; developing technical recommendations for the use of Roundup Ready alfalfa and for weed resistance management strategies; and providing technical and strategic direction for commercialization of Roundup Ready alfalfa in Canada, Mexico, and Argentina.

3. I was raised on a dairy farm in Minnesota, and my family has been in dairy farming for four generations. I am an agronomist by training and have a Bachelor of Science degree in agronomy from the University of Minnesota (1978), a Masters of Science in agronomy from the University of Kentucky (1982), and a Ph.D. in agronomy from The Ohio State University (1994). My doctoral dissertation focused on alfalfa breeding.

4. I first joined Monsanto in 1982, serving first as a Research Biologist II and then as a Senior Research

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[1] ®Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

Biologist until 1986. From 1986 to 1998, I worked at The Ohio State University, first as a Research Associate/Tissue Culture Specialist focusing on plant pathology, then as a Graduate Research and Teaching Assistant in agronomy, and finally as a Post-doctoral Researcher in plant pathology.

5. I returned to Monsanto in 1998, and since then have held several positions of increasing responsibility including: Manager of Agronomic Training for DEKALB Genetics (a Monsanto subsidiary) (1998-1999); Technical Information Specialist (1999-2002); Technology Development Manager for Monsanto's Central Ohio sales team (2002-2003); Product Labels Manager (2003-2005); and my current position with the company. A true and correct copy of my curriculum vitae is attached as Exhibit A to the declaration I have submitted previously in this matter on March 2, 2007 ("Pierson Decl. I").

6. I have personal knowledge of the matters referred to herein and if called upon to testify could and would testify truthfully thereto. Below, I will cover the following topics:

- Background on alfalfa (¶¶ 7-9);
- Stewardship practices for Roundup Ready alfalfa, including:
  —isolation distances for seed fields (¶¶ 11-14);
  —isolation distances and timing for harvest of Roundup Ready alfalfa forage (¶¶ 15-28);
  —cleanup and storage practices (¶¶ 29-31);
  —feral alfalfa (¶¶ 32-34); and
  —weed resistance (¶¶ 35-53);
- Value to forage growers of Roundup Ready alfalfa (¶¶ 54-59);

- Plaintiffs' declarations of Glen Page and William Freese (¶¶ 60-65); and
- Sales of Roundup Ready alfalfa to Japan (¶¶ 66-67).

Background On Alfalfa

7. Alfalfa is a legume grown almost exclusively for animal feed (forage) and harvested primarily in the form of hay. It is a perennial crop, usually grown for three to five years before it is plowed under and a rotation crop is planted for one or more years. During its lifespan, within each growing season, alfalfa is cut (mowed) and harvested at regular intervals. Approximately once per month, it is baled for hay, green chopped, or pastured. Alfalfa is highly valued as livestock feed, providing more nutrition and better digestibility than other feeds.

8. The presence of weed seeds and weed biomass in forage lowers the on-farm or cash market value of the hay and negatively impacts the nutritive value to the livestock fed the hay. Weeds are a major problem in alfalfa, particularly in the alfalfa plants' first year of growth (the seeding year), when the frail alfalfa seedlings are easily out-competed for water, nutrients and space by stronger, faster growing weeds. In the later years of the alfalfa field (or stand), weeds can overtake older, weaker alfalfa plants, thereby lowering the quality and value of hay and forcing earlier termination (plow-down) of the stand.

9. Roundup Ready alfalfa provides an important new tool in combating weeds in alfalfa production. Roundup agricultural herbicides (the active ingredient of which is glyphosate) control more than 100 species of grassy and broadleaf weeds, so they can remove nearly

every species that appears during the alfalfa field lifespan.

Stewardship Practices And Biological Barriers To Gene Transmission From Roundup Ready Alfalfa Forage

10. I have reviewed the Government's proposed order, which was filed with the Court on March 7, 2007. The Government's proposed order would permit the introduction of Roundup Ready alfalfa during the time period that APHIS is preparing an environmental impact statement ("EIS"), subject to certain limitations. The Government's proposed order, and the limitations set forth in that order for the future use of Roundup Ready alfalfa to control gene flow from Roundup Ready alfalfa to conventional or common alfalfa, are supported by science and can be understood and applied both by growers of Roundup Ready alfalfa seed and by Roundup Ready alfalfa forage growers.

Isolation Distances For Seed And Forage, And Timing For Harvest Of Roundup Ready Alfalfa Forage

11. **Isolation Distances for Seed.** Since the early testing of Roundup Ready alfalfa, isolation distances have been established which were more stringent than required for certified seed production. Certified seed standards have been developed to ensure purity greater than or equal to 99%. FGI currently requires that all Roundup Ready alfalfa seed production fields have, at minimum, a foundation class isolation distance to existing non-Roundup Ready alfalfa seed fields of 900 feet, one mile, or three miles isolation for leafcutter bees, alkali bees, or honeybee mediated pollination,

respectively.[2] These isolation distances are 5 to 85 times (depending upon the pollinator) the distance required for certified seed of conventional alfalfa varieties.[3] During six years of testing prior to the deregulation decision, and in the 20 months since the Department's deregulation decision, these distances have proved effective.

12. I have reviewed the Government's proposal for required isolation distances for seed growers. It provides that the following isolation distances be instituted when Roundup Ready alfalfa is grown for seed production: (1) Roundup Ready alfalfa must be planted 1500 feet from any alfalfa fields used for seed production when leaf cutter bees are used to pollinate Roundup Ready alfalfa, and (2) Roundup Ready alfalfa must be planted three miles from any alfalfa fields used for seed production when honey bees are used to pollinate Roundup Ready alfalfa.[4] With those distances, the likelihood of transmission of genetic traits to a conventional or organic crop would be de minimis.

13. The Government's proposed requirement of 1500 feet for isolation for Roundup Ready alfalfa seed production with leafcutter bees limits potential pollen movement to nearly zero. This is approaching nearly double the isolation distance (1500 feet vs. 900 feet) required for foundation seed production designed to

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[2] *See* Mar. 2, 2007 Decl. of Mark H. McCaslin ¶ 10.

[3] *Id.* (citing American Organization of Seed Certifying Agencies (AOSCA) requirements for certified alfalfa seed production, at http://www.aosca.org/about.html).

[4] *See* Mar. 7, 2007 2d Decl. of Neil Hoffman ¶ 7.

achieve 99.90% varietal purity.[5] (Leafcutter bees are known to forage within a few hundred feet of their shelters and in the fields where their shelters (nests) are placed.[6] Additionally pollen flow studies using the Roundup Ready trait as a marker found gene flow at 1500 feet to be less than 0.1%.[7] The following chart summarizes gene flow, using leafcutter bees as pollinators, from a Roundup Ready alfalfa seed crop to a non GE seed crop under conditions that maximize pollination and seed production:[8]

Distance	Gene Flow
500 feet	less than 1.5%
900 feet	less than 0.5%
1500 feet	less than 0.1%
2000 feet	0%

14. The requirement of a 3-mile isolation distance for Roundup Ready alfalfa seed production when using honey bees has been demonstrated to reduce the potential for gene flow to nearly zero. Honey bees

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[5] Seed Certification Standards in California: Alfalfa *available at* http://ccia.ucdavis.edu/seed_cert/alfalfa_seedcert_standards.pdf.

[6] G.E. Bohart. 1972. Management of wild bees for pollination of crops. Annual Review of Entomology 17:287-312.

[7] McCaslin, M., Fitzpatrick and P. Reisen. 2001. Summary of 2000 pollen flow experiment, *available at* http://www.naaic.org/Publications/GeneFlowFGI2000/GeneFlowinalfalfa.html.

[8] Daniel Putnam, Extension Agronomist at University of California, Davis (Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193), attached as Ex. B to Pierson Decl. I.

forage close to their hives. The most effective pollination occurs within a 90 meter radius of the hive.[9] Gene flow of the Roundup Ready marker was measured at less than 0.03% at a distance of 2.53 miles in a study conducted by University of California researchers.[10] The following chart summarizes gene flow, using honeybees as pollinators, from a Roundup Ready alfalfa seed crop to a non-GE seed crop under conditions that maximize pollination and seed production, conditions that are unusual in alfalfa fields:[11]

Distance	Gene Flow
900 feet	1.5%
2500 feet	less than 1%
2.5 miles	less than 0.03%

15. **Isolation Distances For Forage, And Timing For Harvest Of Roundup Ready Alfalfa Forage.** For forage farmers, the likelihood of pollen movement is very low even without any isolation distances. Indeed, the potential for trait movement from a Roundup Ready hay field to a conventional or organic alfalfa hay field is virtually non-existent. There are numerous steps that would be required for the

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[9] Rincker, C., V. Marble, D. Brown, and C. Johansen. 1988. Seed production practices. *In Alfalfa and Alfalfa Improvement*, A.A. Hanson, D.K. Barnes and R.R. Hill, eds. Pgs 985-1021.

[10] Teuber, L. R., et al. 2004. Gene flow in alfalfa under honeybee (*Apis mellifera*) pollination (Abstract). 39th NAAIC, *available at* http://naaic.org/Meetings/National/2004NAACI&TC/2004abstracts/lteuber.pdf.

[11] *See* Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193, attached as Ex. B to Pierson Decl. I.

Roundup Ready trait to move to and participate in organic alfalfa hay production.[12]

16. Roundup Ready alfalfa plants must flower before they can produce pollen. Cross-pollination by insects is the only possible mechanism for transfer of genetic material from Roundup Ready alfalfa plants to other alfalfa plants. Because Roundup Ready alfalfa produced for forage is harvested before flowering, it is highly unlikely that such cross pollination will occur.

17. Even if some limited flowering occurs, the potential for pollen and gene flow between forage fields is extremely low because:

(i) pollination would require the two fields to flower at the same time, which would be rare as the cutting schedules for the two fields would need to be in sync with one another and, because alfalfa is cut in late bud to early bloom stage to maximize hay quality, flowers would be present in low numbers if at all;

(ii) alfalfa requires an insect pollinator (usually leafcutter bees or honeybees) for pollination, and hay production fields are not stocked with bees;

(iii) alfalfa pollinators are generally not attracted to forage alfalfa fields because few flowers are present making the fields poor foraging grounds for the insects; and

(iv) alfalfa does not shed pollen to the wind.

18. Production of alfalfa seed requires seed growers to stock bees on seed production fields. Bees

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[12] *See* Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193.

are not stocked on forage production fields because they are not needed to produce forage and forage fields are cut prior to any significant flowering. Thus, unless a grower were to stock bees on a forage production field and intentionally leave that field uncut so as to permit flowering, and unless flowering in that field and a neighboring field actually occurred at the same time, cross-pollination between the fields would be extremely unlikely.

19. In regions where leafcutter bees are not prevalent, the likelihood of pollination is even lower because honeybees, even if present, mainly collect nectar, not pollen, and are therefore much less likely to cause pollination.[13] Studies have shown that only one honeybee in 100 collects pollen from alfalfa,[14] that only one in five of their floral visits results in pollination,[15] and that honeybees tend to avoid alfalfa if other crop or weed flowers are present.[16]

20. In the highly unlikely event that genetic material from Roundup Ready alfalfa were transferred through pollination to a non-Roundup Ready alfalfa forage field, the frequent cutting of alfalfa makes it highly unlikely that the pollinated plant would be allowed to grow long enough to produce a mature viable seed.

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[13] Cane, J.H. 2002. Pollinating bees (*Hymenopters: Apiformes*) of U.S. alfalfa compared for rates of pod and seed set. J. Econ. Entomol. 95(1): 22-27.

[14] Root, A.I. 1983. The ABC and XYZ of Bee Culture 6-7.

[15] Crane, *supra*.

[16] Teuber, L.R., et al. 2005. Gene flow in alfalfa (*Medicago sativa L.*) when honeybees (*Apis mellifera*) are used as pollinators. 2005 North Central Weed Science Society Proceedings.

21. But even if such a seed were permitted to mature, it is highly unlikely that it would germinate. Alfalfa seeds are not light enough to be transported by wind. Seeds that fall close to the existing "parent" stand are unlikely to survive because of "autotoxicity," a phenomenon resulting from the release by established alfalfa plants of natural toxins that prevent the germination or survival of seeds. Even if seeds were somehow transported away from the existing alfalfa stand, germination and survival is unlikely because of the growing conditions required: alfalfa seed requires seed-to-soil contact and adequate moisture to survive. Seedlings are also easily outcompeted by established vegetation.

22. These factors together make the likelihood of gene transmission from Roundup Ready alfalfa forage fields to other hay fields infinitesimally small. For example, a 2006 peer-reviewed publication from the University of California, which was attached as Exhibit B to Pierson Decl. I, found that, although gene transfer from one hay field to another is theoretically possible, the range of environmental barriers make gene movement very unlikely and the likelihood that a trait such as glyphosate tolerance would show up where it was not intended infinitely small (*i.e.*, far less than 0.001% of field biomass).

23. In the extremely rare event that a pollen grain did move from the Roundup Ready field to an organic field it would have no impact on hay. A stray pollen grain would not change the nature of the organic alfalfa plant it landed on. Only if the organic field was allowed to go to seed and the seed harvested and sold might adventitious presence of the Roundup Ready trait be realized. Alternatively, the seed would need to drop to

the ground, germinate and become established. Alfalfa seedlings are very poor competitors while established alfalfa plants are highly competitive with weeds (and alfalfa seedlings). Established alfalfa plants produce a toxin, medicarpin, that inhibits alfalfa seed germination and establishment.

24. The Government's proposed order provides that, for forage growers, Roundup Ready alfalfa must be planted 165 feet from any alfalfa fields used for certified seed production. This isolation distance for forage growers would make any unintended movement of genetic material extremely unlikely.

25. For instance, the Government's proposed isolation distance of 165 feet from a Roundup Ready alfalfa hay field to certified seed field is the distance required by state seed certification organizations for varietal separation—two alfalfa seed fields of different varieties.[17] During an experiment that used pollinators in a seed field and a hay field containing more blooms (*i.e.*, 20-50%) than will be allowed by the Government's proposed order, an isolation distance of 165 feet was found to reduce pollen-mediated gene flow to under 0.2% for leaf cutter bees and 0.3% for honey bees.[18] These study numbers fell to zero at a distance of 365 feet for honey bees.[19]

26. As identified above, the likelihood of movement of genetic material is extremely low to non-existent from a forage field in part because farmers

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[17] Seed Certification Standards in California: Alfalfa.

[18] Teuber, L.R. & S.N. Fitzpatrick. 2007. Proceedings of the Alfalfa Seed Production Symposium, March 5-6, 2007, attached as Attach. 3 to the Mar. 7, 2007 2d Decl. of Neil Hoffman.

[19] *Id.*

mow or harvest forage in the late bud to early bloom stage. Thus, the frequent cutting of alfalfa makes it highly unlikely that the pollen would be available to be transferred to seed production fields. In geographies where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, Roundup Ready alfalfa must be harvested at or before 10% bloom to minimize potential pollen flow. In addition, and as explained above, the chances that two fields would flower at the same time is remote, there are no insect pollinators used on hay production fields, alfalfa pollinators are not attracted to forage production alfalfa fields, and alfalfa does not shed pollen to the wind. The Government's proposal would also require mowing at certain intervals depending upon whether the isolation distances were within certain limits.

27. In its proposed order, the Government also proposes that, in order to minimize gene flow from Roundup Ready alfalfa to common alfalfa seed production: (1) all Roundup Ready alfalfa be harvested prior to seed set; (2) all Roundup Ready alfalfa located within 165 feet of any alfalfa field grown for common seed production shall be harvested pre-bloom; and (3) Roundup Ready alfalfa located between 165 and 500 feet from any alfalfa field grown for seed production shall be harvested at or before 10% bloom.

28. The chances that common alfalfa will be contaminated through the use of the Government's proposed measures are extremely low. Monsanto currently prohibits seed production from Roundup Ready alfalfa and we monitor and steward this

requirement. In order for pollen flow to occur between Roundup Ready alfalfa for hay production and an alfalfa field allowed to go to seed resulting in "common seed" production, both the hay field and the "seed" field must be in bloom at the same time. This may not always occur but the further requirement for harvest of Roundup Ready Alfalfa pre-bloom within 165 feet of common seed production and prior to 10% bloom within 165 to 500 feet will strictly limit pollen flow to common seed production. These restrictions are supported by both seed certification standards and the pollen flow studies cited above.

Cleanup And Storage Practices

29. With regard to cleaning practices, the Government proposes that: (1) cleaning procedures for planters, harvesters, tractors and tillage equipment be submitted to and approved by APHIS prior to implementation; (2) cleaning procedures will be designed to minimize the risk of Roundup Ready alfalfa seed and hay movement from the authorized production site; and (3) all equipment will be cleaned in accordance with the approved procedures before the equipment leaves the farm on which it came in contact with Roundup Ready alfalfa. Furthermore, the Government's proposed order requires specific seed handling techniques to minimize commingling after harvest.

30. Requiring growers to clean their equipment following planting, tilling or harvesting Roundup Ready alfalfa will eliminate the potential for mechanical mixing if equipment is moved from farm to farm. The unique purple seed coating used for Roundup Ready alfalfa seed will make it easier for growers to see any seed remaining in their planter or

clinging to their equipment. Since Roundup Ready alfalfa will not be allowed to go to seed and growers will harvest Roundup Ready alfalfa in pre-bloom to early bloom stage, the potential for movement of viable seed with hay equipment is essentially zero. Additionally, cleaning baling equipment after baling Roundup Ready alfalfa hay removes the potential for mechanical mixing of forage where growers or customers might be sensitive to the presence of Roundup Ready alfalfa in their hay. Thus, with these practices in place, the requirements would be more than sufficient. In addition, the following measures, which parallel the Government's proposal, are already required by Monsanto in its contract with growers: growers are required to mitigate seed production, not produce or save seed, nor transfer seed to others.

31. The Government's proposed order also states that "APHIS will require that immediately after harvest growers and seed producers store RRA seed in specifically designated and clearly labeled containers until seed is transferred to Forage Genetics Inc." This is simply proper seed handling that any responsible seed company would use to ensure varietal purity. I have visited the FGI seed production/processing facility in Nampa, Idaho, as well as the coating facility they work with, and FGI uses these measures as part of their best management practices for Roundup Ready alfalfa seed production. In addition to a clear best management practices program for Roundup Ready alfalfa seed production and processing, very sensitive,

rapid, seed testing kits are available from Strategic Diagnostics, Inc. and Envirologix.[20]

Feral Alfalfa

32. Feral alfalfa populations exist throughout the country where alfalfa is grown commercially. The origin of these populations is not well established but they are believed to have developed from roadside plantings, abandoned fields, seed spills and movement by birds or other wildlife. Feral alfalfa should be controlled around and near seed production fields to ensure varietal purity. Pollen flow from feral alfalfa, even feral alfalfa that might contain the Roundup Ready trait, would have no impact on hay production—organic, conventional or Roundup Ready alfalfa—as hay fields are cut in late bud to early flower stage for best forage quality. Any pollen movement from a feral

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[20] Additionally, the Government's proposed order states that "APHIS will require that growers of RRA identify and keep records of all alfalfa crops grown within 500 feet of their fields" and that "APHIS will require that RRA shall not be used for livestock grazing purposes or in a mixed grass pasture in order to ensure that the harvesting and management requirement specified in the judgment are met." The records requirement is a good neighbor policy. A grower could readily identify other alfalfa crops within 500 feet of their Roundup Ready alfalfa field. This requirement would not be necessary in areas where seed—certified or common—is not produced as hay to hay transmission is extremely unlikely. Furthermore, Roundup Ready alfalfa offers some exceptional opportunity for animal grazing with the opportunity to control noxious and toxic weeds in pastures. Two varieties of grazing tolerant Roundup Ready alfalfa have been developed. Grazing does pose a slightly higher risk for flower production and seed development if a pasture is not adequately stocked with animals or is not properly managed. It is reasonable for APHIS to require that Roundup Ready Alfalfa not be used for grazing until the EIS is completed.

population would not impact the nature of the hay produced.

33. Seed growers should clear feral alfalfa within the limits of the applicable isolation distances as a matter of practice from any areas surrounding seed fields to ensure that pollen from feral alfalfa does not affect the genetic traits of the Roundup Ready alfalfa, conventional or organic seed crop. The movement of a genetic trait from a forage field to feral alfalfa is extremely unlikely for the reasons set forth above and for the following reason: forage alfalfa fields are not stocked with pollinators and are not attractive to wild pollinators since they are cut in the late bud to early flower stage making foraging less profitable for the insect.

34. Additionally, there are at least two effective methods to control pollen flow to and from feral alfalfa: mowing to prevent flowering or seed set or the use of herbicides. Dicamba alone, 2,4-D alone or dicamba tank mixed with 2,4-D are cost effective treatments for the control of feral alfalfa or for stand take out of either Roundup Ready or conventional alfalfa.[21] These treatments will control or eradicate feral alfalfa within the isolation distances in the Government's proposed order. Certainly, if feral alfalfa were eradicated or mowed within the isolation distances proposed by the Government for seed production fields, the chances of spread of the genetic material would again be extremely remote. Furthermore, because glyphosate is not the most effective treatment for controlling feral alfalfa and other inexpensive and more effective

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[21] Guide for Weed Management in Nebraska *available at* http://www.nlc.state.ne.us/epubs/U2250/H001.0130-2007.pdf.

treatments are available, glyphosate would not need to be used on feral alfalfa thereby providing no selective advantage to the Roundup Ready trait in feral alfalfa populations.

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Value To Forage Growers Of Roundup Ready Alfalfa

54. Roundup Ready alfalfa is engineered to be tolerant to glyphosate, the active ingredient in Roundup agricultural herbicides. Weed control is critical during the first year, when the alfalfa is delicate and the weeds are most aggressive. The use of Roundup agricultural herbicide over the top of Roundup Ready alfalfa, which is known as the Roundup Ready alfalfa system, provides broad-spectrum weed control relieving the alfalfa seedlings from competition for light and moisture by weeds. Giving the young alfalfa a good start promotes a full, strong crop of alfalfa in the field in later years, minimizing thin spots in the field where weeds could later take root. This strong crop results in high yield and high quality hay throughout the multi-year stand life, meaning better nutrition for livestock and higher economic value for the grower.

55. The unavailability of Roundup Ready alfalfa will mean that growers are compelled to use less effective and more toxic herbicide alternatives with lower yield and many other collateral problems.

56. Traditional weed control programs used for alfalfa production pose significant practical limitations for growers. These limitations impose upon growers significant additional costs because growers are required to expend extra efforts and to purchase

additional materials for use. Additionally, traditional weed control programs often require growers to use increased levels of herbicides that increases toxicity. The major herbicides used include Buctril 4EC, Eptam, Paraquat, Velpar, Butyrac, Raptor, Poast, Pursuit, Kerb, and Treflan. Among the limitations on non-RRA alfalfa herbicides are the following:

a. **Application timing restrictions.** Roundup agricultural herbicides have the widest window of application for over-the-top use in Roundup Ready alfalfa compared to other herbicides labeled for use in alfalfa. Roundup agricultural herbicides can be applied to control weeds prior to planting, applied prior to crop emergence and from alfalfa emergence from the soil until five days prior to harvest. Other herbicides labeled for use in alfalfa have specific timing restrictions for reasons of crop safety or residue restrictions for the harvested crop. For example Buctril® 4EC should not be applied prior to the 4 tri-foliate leaf stage and must be applied a minimum of 30 days prior to harvest.[39] Some traditional herbicides used for alfalfa may only be used prior to planting alfalfa such as Eptam® or when alfalfa is dormant and not actively growing, such as Paraquat and Velpar herbicides. Some herbicide can only be applied early in the life of the stand because they may carryover to damage rotational crops. The Velpar® AlfaMax™ MP specimen product label, for example, restricts growers from planting to any other crop for 12 months, and after 12 months and up to 24 months, following application only corn, root crops or sugarcane

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[39] Buctril 4EC specimen product label; http://www.cdms.net/ldat/ld293002.pdf.

can be planted.[40] In addition to these restrictions in areas of low rainfall or where drought conditions have occurred the Velpar label recommends a field bioassay the results of which can further extend the rotational restrictions. A field bioassay involves planting a portion of the treated field with the rotation crop and monitoring it for symptoms of crop injury.

b. **Application restrictions related to air temperature, soil type, and water.** The excellent crop safety of Roundup Ready alfalfa system allows growers to be less concerned about air and soil temperatures, soil type and soil moisture or rainfall. There are no concerns about the effect of air temperature on herbicide crop safety with Roundup agricultural herbicides compared to traditional herbicides. For example, Buctril, whose active ingredient is bromoxymil, should not be applied when temperatures following application are expected to exceed 70°F at application and for up to 3 days following application.[41] If Butryac, whose active ingredient is 2,4-DB, is applied, rainfall or irrigation within 7 to 10 days following application can result in unacceptable crop injury.[42] Application rates for Eptam differ based on soil texture. On coarse soils Eptam rates must be reduced to 15 lb/acre.[43]

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[40] Velpar® AlfaMax™ MP specimen product label; http://www.cdms.net/ldat/ld6GG001.pdf.

[41] Buctril 4EC specimen product label; http://www.cdms.net/ldat/ld293002.pdf.

[42] Agri Star® Butyrac® 200 specimen product label; http://www.cdms.net/ldat/ld4JG000.pdf.

[43] Eptam® specimen product label; http://www.cdms.net/ldat/ld7P1000.pdf.

c. **Narrow weed control spectrum, which requires tank mixing or application of multiple products**. Roundup agricultural herbicides are broad-spectrum herbicides meaning they can control a wide range of annual and perennial grasses and broadleaf weeds. The University of California Cooperative Extension Weed Research and Information Center website lists weed control by herbicide active ingredients based on local observations. They indicate that glyphosate, the active ingredient in Roundup agricultural herbicides controls or partially controls 68 weeds and provides partial control of an additional 16 weeds.[44] Imazamox, the active ingredient in Raptor, controls 25 weeds and provides partial control of 25 additional weeds. EPTC, the active ingredient in Eptam® controls 41 weeds and partial control of an additional 11 weeds. Some traditional alfalfa herbicide are considered selective in that they control only broadleaf weeds, such as Butyrac, or only grasses, such as Poast®. Butryac®, whose active ingredient is 2,4-DB, controls 20 broadleaf weeds and provides partial control of an additional 16 broadleaf weeds. Sethoxydim, the active ingredient in Poast®, controls 16 grasses and provides partial control of an additional three grasses.

d. **Significant risk of crop injury**. The Eptam label warns that "temporary crop stunting and sealing of first leaves will occur if conditions for germination and crop growth are not good."[45] These

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[44] http://ucce.ucdavis.edu/specialsites/weed%5Fsept/herbicide_selected.asp.

[45] Eptam® product label; http://www.cdms.net/ldat/ld7P1000.pdf.

"not good" conditions are characterized by cool, wet weather, conditions that are common in spring in the upper Midwest and Northeast where alfalfa is spring planted. Butryac, whose active ingredient is 2,4-DB, can result in seedling twisting.[46] The Raptor label notes the potential for crop injury to seedling alfalfa stating that "there may be a temporary reduction in growth."[47] Raptor® and Pursuit®, two herbicides labeled for postemergence applications in seedling alfalfa, can cause significant crop injury, reducing crop yield significantly.[48] Buctril applications can result in stunting and leaf burning or bleaching symptoms.

e. **Carryover concerns and rotation restrictions.** Roundup agricultural herbicides have no residual soil activity meaning they do not persist in the soil to impact or injure the next crop. In fact they are rapidly inactivated and broken down in the soil. The maximum crop rotation restriction following an application of Roundup WeatherMAX is 30 days.[49] Traditional herbicides used in alfalfa production can persist in the soil for months to years, limiting rotational crop options. Rotational restrictions for Raptor® for most crops are 18 months from the time of the last applications but range from three months for

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[46] Agri Star® Butyrac® 200 product label; http://www.cdms.net/ldat/ld4JG000.pdf.

[47] Raptor® specimen product label; http://www.cdms.net/ldat/ld20T037.pdf.

[48] Forage Variety Update for Wisconsin, 2006 Trial Results, http://www.uwex.edu/ces/forage/pubs/A1525-2006.pdf.

[49] Roundup WeatherMAX® specimen product label; http://www.cdms.net/ldat/ld5UJ029.pdf.

wheat to 26 months for sugarbeet.[50] Rotational restrictions for Pursuit can be up to 40 months depending on the crop.[51]

f. **Substantial pre-harvest interval restrictions.** Roundup agricultural herbicides have a very short preharvest interval, the time required by the EPA-approved herbicide product label between application of the herbicide and harvest of the crop. The preharvest interval for Roundup Ready alfalfa following an application of Roundup WeatherMAX is five days.[52] Preharvest intervals for traditional alfalfa herbicides range from 14 days for hay harvest following an application of Poast®, 30 days for an application of Pursuit® and as long as 120 days following an application of Kerb.®[53]

g. **Incomplete control of some weeds.** Roundup agricultural herbicides provide broad-spectrum weed control of both perennial and annual grass and broadleaf weeds. Thirty-eight weeds are known to be resistant to ALS herbicides such as Pursuit and Raptor. Adding another herbicide mode of action, glyphosate, offers an additional option for control of ALS-resistant weeds in Roundup Ready alfalfa.

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[50] Raptor® specimen product label; http://www.cdms.net/ldat/ld20T037.pdf.

[51] Pursuit® specimen product label; http://www.cdms.net/ldat/ld798017.pdf.

[52] Roundup WeatherMAX® specimen product label; http://www.cdms.net/ldat/ld5UJ029.pdf.

[53] 2007 Weed Control Guide for Ohio and Indiana, Forage Weed Control http://www.btny.purdue.edu/pubs/WS/WS-16/LegumeHerb.pdf.

h. **Variability in product performance.** Herbicides like Treflan™ TR-10™ require rainfall to activate them.[54] Too little or too much rainfall can either fail to activate the herbicide or wash the herbicide out of the soil zone where weed seeds are germinating resulting in less than optimum weed control

i. **Increased toxicity.** Relative to other traditional alfalfa herbicides, Roundup agricultural herbicides are quite safe. Glyphosate is essentially non-toxic. Other traditional alfalfa herbicides are more toxic. The Buctril label states that it is toxic to fish and wildlife. The Eptam label alerts the user that the active ingredient is a teratogen and a special supplemental label for California requires additional personal protection equipment and exposure limits for handlers.

57. By contrast, there are several key benefits to Roundup Ready alfalfa systems that are not present for alternative herbicides. Roundup Ready alfalfa will allow for glyphosate applications at pre-plant, pre-emergence, and/or post-emergence timings in both seedling and established Roundup Ready alfalfa. As a result, the Roundup Ready alfalfa system offers control of weeds when most appropriate. Other benefits of the Roundup Ready alfalfa system include:

a. **Excellent broad-spectrum control and flexibility for season-long weed control.** Using the Roundup Ready alfalfa system, growers can control perennial weeds. Many products currently in use have a narrow window of application based upon specific

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[54] Treflan T-10 specimen product label; http://www.cdms.net/ldat/ld02R030.pdf.

weed size or crop stage. In-crop Roundup agricultural herbicide applications can be made from crop emergence up to five days before cutting, regardless of crop stage. This flexibility will provide the grower with a wider window of application and allow application timing based upon weed pressure, not on crop or weed stages.

b. **Control weeds that are poisonous to livestock and noxious parasitic weeds.** By using the Roundup Ready alfalfa systems, growers can control weeds such as fiddleneck, starthistle, and groundsel,[55] which are poisonous to livestock. Similarly, the Roundup Ready alfalfa system allows growers to control noxious parasitic weeds such as dodder in forage and seed production.[56]

c. **Greater success in stand establishment.** Weed competition for moisture, nutrients, and light is detrimental to the establishment of new alfalfa stands and to the subsequent quality and yield of hay. As noted above, currently available products are hampered with limitations that often force growers to use alternative approaches such as: (1) seeding with a cover or companion crop, which may suppress weeds but also competes with alfalfa; (2) delaying first cutting for a minimum of 60 days, which sacrifices hay quality to allow surviving alfalfa to progress beyond competing weeds; or (3) delaying seeding of new stands until late

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[55] University of California Cooperative Extension Weed Research and Information Center website, http://ucce.ucdavis.edu/specialsites/weed%5Fsept/herbicide_selected.asp.

[56] Canevari, M, T. Lanini and S. Orloff. 2006. Roundup Ready Alfalfa for Stand Establishment and Special Weed Issues, http://alfalfa.ucdavis.edu/symposium/proceedings/2006/06-77.pdf.

summer or early fall when there is less weed competition. All of these alternative approaches result in considerable loss in a grower's first-year production that can reach $300 per acre. The flexibility and ease of use of Roundup agricultural herbicides permits growers to seed new stands and eliminate weeds early with little risk of stand, yield, or quality loss.

d. **Improved forage quality and higher yields**. Weed infestations are a major limiting factor in the production of high-quality alfalfa forage. The value per ton of alfalfa forage to both commercial hay and livestock producers is based largely upon forage quality. A weed infestation of as little as 10% of the field can result in as much as a 15% decrease in quality and a significant decrease in the dollar per ton value. Put simply, high-quality forage commands a higher price per ton. Current hay prices in California demonstrate a $20 to 30 per ton cash premium for "premium/supreme" quality hay compared to "good" quality hay.[57] The superior weed control performance of Roundup agricultural herbicides with Roundup Ready alfalfa leads to healthier and more vigorous stands that are better able to compete with weeds and will generate higher quality forage and higher alfalfa yields.

e. **Potential for reduced cultivation**. The environmental benefits of reduced tillage—such as erosion control, reduced use of fossil fuels, and improved soil quality— are well known to growers. Many of the available weed control products used in alfalfa production require immediate soil incorporation

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[57] California Weekly Hay report http://www.ams.usda.gov/mnreports/ML_GR311.txt.

and thorough tillage is usually recommended. These added tillage operations would be eliminated with the use of Roundup agricultural herbicides in Roundup Ready alfalfa in many geographic areas.

f. **Improved weed control flexibility in established stands.** Because alfalfa is a perennial crop, perennial weeds often reestablish themselves each season. These weeds then compete with the alfalfa for water and nutrients reducing alfalfa growth, and contributing weeds to the harvested forage which affects the quality. If not controlled, perennial weeds effectively shorten the productive life of the stand. Winter annual weeds are also a serious problem where non-dormant alfalfa varieties are grown and harvested all year long. These weeds tend to flourish during the cooler winter months and existing products are limited in their effectiveness in controlling such weeds during this time period. The use of Roundup agricultural herbicides will give growers much greater flexibility in controlling perennial weeds and winter annual weeds in established stands.

g. **Alternate mode of action.** The in-crop use of Roundup herbicides in alfalfa will provide growers with an additional, unique mode of action for managing herbicide resistant weeds. Currently alfalfa producers rely heavily on ALS herbicides, such as Pursuit or Raptor for post-emergent weed control in seedling alfalfa. The introduction of Roundup Ready alfalfa and Roundup agricultural herbicides introduces a new mode of action for weed control and managing existing weeds tolerant or uncontrolled by traditional alfalfa herbicides.

h. **Excellent crop safety.** Other herbicides labeled for use in alfalfa can cause crop injury,

particularly when applied at the incorrect crop stage under stressful environmental conditions. This reduction in the potential of herbicide crop injury, along with greater weed control, provides growers with the opportunity to maximize crop yield.

i. **Export benefits for Japanese hay buyers.** Hay buyers often have very specific desires for hay based upon color, stem thickness and tested quality. Not all buyers have the same parameters for selecting and purchasing a lot of hay. While some buyers do not wish to purchase Roundup Ready alfalfa hay, others may come to prefer it because of the lack of weeds and reduced residue of residual, persistent pesticides. Residue from certain residual herbicides can cause problems as residues become concentrated in the manure of dairy animals fed hay treated with more persistent pesticides. This manure, when applied to plants for vegetable production, has resulted in crop injury. These herbicides have been added to a list of pesticides that are not allowed for use in alfalfa sold to Japan. Glyphosate, the active ingredient in Roundup agricultural herbicides, rapidly breaks down in soil and has no residual activity like some of the other herbicides used to control weeds in alfalfa.

58. The following picture demonstrates the benefits of using Roundup Ready alfalfa systems. On the left is Roundup Ready alfalfa treated with Roundup WeatherMAX herbicide and on the right is the same alfalfa variety that has not been treated with an herbicide. The presence of weeds in the untreated alfalfa is dramatically higher than in the Roundup Ready alfalfa.

[Picture omitted]

59. If growers are prevented from planting Roundup Ready alfalfa, they may have no other choice than to choose to plant other varieties of alfalfa such as common or VNS (variety not stated) seed with less yield potential than the elite germplasm found in Roundup Ready alfalfa instead. As a result, the growers will be required to use significantly more toxic, persistant and soil mobile herbicides with less crop safety to control weeds and promote stand establishment and prolong stand life, possibly including Buctril, Eptam or Velpar. These herbicides are more toxic than glyphosate because they are toxic to fish and wildlife, teratogenic or corrosive.

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Sales Of Roundup Ready Alfalfa To Japan

66. In their Opposition and Objections to Defendants' Motion to approve APHIS' Proposed Judgment, which I have read, Plaintiffs state that, "[w]hile it is true that the Japanese government has legally approved the sale of Roundup Ready alfalfa, American exporters and Japanese importers agree that the Japanese market continues to refuse genetically engineered alfalfa."[65] This statement is incorrect.

67. Purchases and shipments of hay are between the buyer and the seller. Although some buyers for export market may not be purchasing hay from Roundup Ready alfalfa, other Japanese buyers are. In spring 2006, rain in western Washington damaged much of the hay, reducing the quality and making it undesirable to Japanese buyers. Japanese hay buyers sought hay near Ellensberg, Washington. High

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[65] Pls.' Opp'n at 9 (citing Evans Decl. ¶¶ 6-10; Gauntt Decl. ¶¶ 7-9; Oishi Decl. ¶¶ 3-7).

quality, first cut Roundup Ready alfalfa hay was available. Thus, Ward-Rugh exported Roundup Ready alfalfa hay to Japan, which was produced by Steve Rossbeck Farms in Ellensberg, Washington. The exporters and the Japanese buyers were very pleased with the forage quality and the weed free condition of the Roundup Ready alfalfa. The Japanese buyers came back to the grower requesting additional hay from the later cuttings, which was then unavailable because it had already been sold to other hay customers.

I declare, under penalty of perjury, that the forgoing is true and correct to the best of my present knowledge.

Executed this 23rd day of March 2007 in St. Louis, Missouri.

/S/
Paulette E. Pierson, Ph.D.

Attorney Signature Attestation

I, Holly J. Tate, counsel for Monsanto Company, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

/S/
Holly J. Tate

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **DIRECT TESTIMONY OF KENT J. BRADFORD REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. My name is Kent J. Bradford. My business address is Seed Biotechnology Center, University of California, Davis, California.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am Professor of Plant Sciences and Director of the Seed Biotechnology Center, at the University of California, Davis.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I received a BS in Biochemistry and a MS in Horticulture, both from Michigan State University. I received my PhD in Plant Physiology from the University of California, Davis, in 1981. My primary research interests involve seed biology, including the molecular biology and physiology of seed development, dormancy and germination, and the storage, enhancement and utilization of seed for agricultural purposes. Since 1995, my research on seed biology has focused to a large extent on plant biotechnology. A copy of my curriculum vitae is attached as Exhibit A.

Q. WHAT IS THE SEED BIOTECHNOLOGY CENTER?

A. The Seed Biotechnology Center is a unit of the College of Agricultural and Environmental Sciences, and its mission is to mobilize the research, educational and outreach resources of the University of California, in partnership with the seed biotechnology industry, to develop and commercialize new germplasm and seed technologies for agricultural and consumer benefit.

Q. WHEN WAS THE SEED BIOTECHNOLOGY CENTER FOUNDED?

A. 1999.

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. I will testify on the issues of gene flow and stewardship associated with new varieties, like herbicide-tolerant Roundup Ready alfalfa.

Q. HAS THE SEED BIOTECHNOLOGY CENTER PLAYED A ROLE IN THE DEVELOPMENT OF ROUNDUP READY ALFALFA?

A. Yes. Since California is a leading state in the production of both alfalfa and alfalfa seed, the Seed Biotechnology Center was interested in a new technology, like Roundup Ready alfalfa, which has the potential to increase yield at lower costs with fewer environmental impacts than other herbicides. In cooperation with other faculty and cooperative extension personnel, the Seed Biotechnology Center conducted collaborative research with Monsanto and Forage Genetics to evaluate various aspects of forage and seed production in California with alfalfa varieties genetically engineered for resistance to glyphosate, the active ingredient in Roundup herbicide. These trials were conducted under APHIS permit and notification guidelines and were included in the original Environmental Assessment of Roundup Ready alfalfa. A summary of those studies has been published by the University of California Division of Agriculture and Natural resources in Publication 8153, "Roundup Ready Alfalfa: An Emerging Technology" (http://ucce.ucdavis.edu/files/filelibrary/5283/17270.pdf). This publication was first distributed at the National Alfalfa Symposium in San Diego in December 2004, six months prior to deregulation of Roundup Ready alfalfa. Over 3000 of these publications have been

distributed to growers, breeders and the seed industry at various alfalfa meetings nationally. The results were also presented in March 2005 at the California Seed Association annual meeting. The issues surrounding gene flow in alfalfa, as well as how Roundup Ready alfalfa fits into a crop growing system to manage weeds and hay production, have been extensively researched by public scientists and communicated to the industry.

II. GENE FLOW IN ALFALFA

Q. WHAT WAS THE PURPOSE OF THE TRIALS conducted WITH RESPECT TO ROUNDUP READY ALFALFA?

A. One purpose of the trials was to evaluate the potential for pollen transfer from Roundup Ready alfalfa to both cultivated and feral alfalfa, since alfalfa is pollinated by bees. As documented in the original petition for deregulation and APHIS' Environmental Assessment, the potential biological and environmental risks associated with this pollen transfer have been thoroughly evaluated and determined to be low or nonexistent.

Q. DID THE SEED BIOTECHNOLOGY CENTER ALSO RESEARCH THE OPPORTUNITY FOR GENE TRANSFER ASSOCIATED WITH SEED PRODUCTION?

A. Yes. The Center conducted research regarding the distance that pollen could be transferred by bees from a source plot containing Roundup Ready alfalfa to trap or receiver plots of conventional alfalfa. After seed maturity, the seeds from the trap plots were harvested, planted, and the seedlings were sprayed with Roundup.

Only the seedlings, resulting from cross-pollination with pollen from the Roundup-resistant source plot would survive this treatment, and the number of survivors relative to the total number of seeds planted gives an estimate of the percentage of outcrossing due to pollen transfer. These studies showed that less than 1% of seeds were Roundup resistant at 3000 ft and less than 0.1% at about 1.5 miles from the source plot. The data are available in Publication 8153, cited previously. Based on this research, guidelines were established for the isolation of seed production fields of Roundup Ready alfalfa in California using honey bee pollination. Forage Genetics agreed to a three-mile isolation distance, twice that required to reduce cross pollination below 0.1%.

Q. IN YOUR OPINION, WHAT IS THE POTENTIAL FOR POLLEN TRANSFER BETWEEN ROUNDUP Ready ALFALFA PRODUCED FOR SEED AND NON-GENETICALLY MODIFIED ALFALFA?

A. Extremely low. As California alfalfa seed growers have extensive experience in meeting seed certification guidelines and maintaining varietal purity via implementation of appropriate isolation distances and seed handling practices, pollen flow and stewardship issues with these new varieties can be accommodated using guidelines and practices that are well established in the seed industry. To facilitate this effort, the Seed Biotechnology Center convened two separate meetings, one at Davis in the Sacramento Valley on January 27, 2005, and one in the Imperial Valley of California on October 4, 2005, where

industry representatives were invited to express their concerns regarding the introduction of Roundup Ready alfalfa and potential impacts upon seed purity and marketing. At these meetings, the scientific information on pollen flow was reviewed, interested parties voiced their concerns, and a consensus was ultimately achieved by identifying seed production practices that would allow coexistence of Roundup Ready alfalfa and both conventional and organic alfalfa farming. A summary of the January 2005 meeting can be obtained at http://ucce.ucdavis.edu/files/filelibrary/5283/22000.pdf. The consensus was possible in large part because Forage Genetics agreed to establish a three-mile isolation distance around its Roundup Ready alfalfa seed production fields, which was more than twice the distance that our study determined would be necessary to reduce potential outcrossing to less than 0.1%. In addition, due to different production practices in the Sacramento Valley and the Imperial Valley, particularly the historic practice of some growers in the Imperial Valley of shifting particular fields from hay production to seed production during a growing season, it was agreed that Roundup Ready alfalfa seed would not be sold for production in the Imperial Valley. Thus, considerable communication and planning took place prior to the initial introduction of Roundup Ready alfalfa to identify practices that would assure coexistence and continued market access among different segments of the alfalfa industry.

III. COXISTENCE

Q. WHAT IS "COEXISTENCE"?

A. Coexistence is the "simultaneous production of agriculture products within a common geographical area in which distinctly different production methods are used" (Ronald and Fouche, 2006, http://anrcatalog.ucdavis.edu/pdf/8188).

Q. IS COEXISTENCE A NEW TYPE OF AGRICULTURAL PRODUCTION SYSTEM?

A. No. Agricultural production virtually always functions in a coexistence mode. Growers manage their own crops and communicate with their neighbors to allow those using different production methods to each attain their market goals. Diverse crop types and varieties are routinely grown in close proximity without compromising market value. For example, rape seed and canola are both the same species, but rape seed oil is not edible while that of canola is. Growers have been producing both crops since the 1950's using coexistence principles. Similar examples can be cited from many crops, such as field corn and sweet corn or popcorn, and diverse types of rice (long grain, short grain), cotton (Acala, Pima), and sunflowers (confectionary and oil types).

Q. DO WE HAVE ANY EXPERIENCE WITH COEXISTENCE OF GENETICALLY MODIFIED CROPS AND NON-GENETICALLY MODIFIED CROPS PRIOR TO ROUNDUP READY ALFALFA?

A. Yes, approximately 90% of the US soybean and cotton production and almost half of US corn production uses varieties developed using genetic

engineering techniques. Growers and marketers of these commodities have developed practices and marketing strategies that have enabled them to meet diverse market standards for these crops.

Q. IN YOUR OPINION, IS COEXISTENCE DESIRABLE?

A. Yes. In fact, it is essential to all of agriculture that growers cooperate to allow each the opportunity to use the production methods and tools that can achieve their market goals.

Q. WHAT ARE THE NECESSARY CONDITIONS FOR COEXISTENCE?

A. There are a number of common practices employed to provide for successful coexistence. Those practices include: (1) Pre-production practices such as communication among neighbors, identification of the varieties and practices being used, and recordkeeping; (2) In-field production practices, such as isolation distances or barriers to pollen flow, buffer mechanisms to reduce pollen flow, and pest resistance management plans; and (3) harvest and post-harvest practices, including sanitation (removal of weeds and off-types), segregation of the harvested products into appropriate market channels, and market requirements that are established based upon the suitability of the product for the intended use.

Q. HOW DO GROWERS LEARN ABOUT THE MANAGEMENT PRACTICES REQUIRED FOR SUCCESSFUL COEXISTENCE?

A. There are a number of sources. The Seed Biotechnology Center has published peer-reviewed guidelines specifically targeted to facilitate coexistence among different types of production systems in maintaining seed purity

(http://anrcatalog.ucdavis.edu/pdf/8189.pdf). Dr. Daniel Putnam, Cooperative Extension Specialist at UC Davis, has published a peer-reviewed bulletin specifically addressing procedures and practices to enable coexistence of diverse production systems incorporating Roundup Ready alfalfa (http://anrcatalog.ucdavis.edu/pdf/8193.pdf). These publications are part of a series of fourteen peer-reviewed fact sheets and grower guidelines specifically addressing coexistence issues in agriculture (see http://sbc.ucdavis.edu/Publications/Agricutural_Biotechnology_in_California_(ABC)_Series.htm). In addition, the California Seed Association (http://calseed.org/) has an active Plant Breeders and Biotechnology Committee in which stewardship issues are discussed and practices acceptable to the industry are developed. The American Seed Trade Association (www.amseed.org) serves a similar function on a national level. In the case of Roundup Ready alfalfa, growers, who are required by contract with Monsanto and FGI to implement the production practices required for effective coexistence, can also rely on those companies to provide useful information.

Q. HOW ARE ISOLATION DISTANCES AND CROSS-POLLINATION STANDARDS ESTABLISHED?

A. Isolation distances and cross-pollination standards are established based upon collective industry experience and market requirements. The standards are based upon the crop characteristics, such as whether it is primarily self-pollinated or

cross pollinated, whether pollen is transported by wind or insects, and pollen longevity. The isolation distances are established from experience for each crop to enable seed producers to meet the standards for genetic purity expected in the marketplace, which also vary with the crop type. These standards are generally higher for seed than they are for general commodities, and seed certifying agencies or seed company quality assurance personnel monitor, audit, inspect and test seed crops to assure genetic purity (see http://www.aosca.org/).

Q. CAN THE MAINTENANCE OF ISOLATION DISTANCES BE EFFECTIVELY MONITORED?

A. Yes. The California Crop Improvement Association (the official seed certifying agency) and the Seed Biotechnology Center have developed a web-based isolation mapping system to allow seed producers to coordinate their field locations and isolation distances for a number of seed crops, including alfalfa (see http://ccia.ucdavis.edu/crop/MapMainPage.htm). This mapping system has been incorporated into the California alfalfa coexistence framework by providing a mechanism by which non-GM and organic growers could determine whether any Roundup Ready alfalfa seed production was occurring within a specified distance from their fields.

IV. AP SENSITIVE MARKETS AND ORGANIC CERTIFICATION

Q. WHAT IS "ADVENTITIOUS PRESENCE"?

A. "Adventitious presence" (AP) is the term used to indicate the unintended occurrence of material,

GM seeds or hay in this case, in an agricultural commodity.

Q. ARE THERE MARKETS FOR U.S. PRODUCED ALFALFA SEED OR FORAGE THAT ARE SENSITIVE TO ADVENTITIOUS PRESENCE?

A. The vast majority of the alfalfa hay and seed produced in the U.S. is used domestically and is not sensitive to adventitious presence. Normal management practices for alfalfa hay or certified seed production are adequate to meet these market requirements. There are specific markets/customers that are AP-sensitive (e.g. specific export markets). Protein-based test kits have been developed and are now widely used to identify and segregate Roundup Ready vs conventional alfalfa hay and seed. These test kits coupled with the extraordinary isolation standards imposed as part of the Roundup Ready stewardship requirements should allow alfalfa hay and seed producers and marketers to meet the needs of AP-sensitive markets.

Q. ARE ANY STANDARDS IN PLACE IN THE UNITED STATES REGARDING THE AMOUNT OF NON-GM MATERIAL THAT CAN BE PRESENT IN PRODUCTS CERTIFIED AS "ORGANIC"?

A. The National Organic Program does not specify any threshold or maximum with respect to the adventitious presence of GM materials in organic products.

Q. WHAT IS THE "NATIONAL ORGANIC PROGRAM"?

A. The National Organic Program is the program in the USDA that establishes the criteria and practices that allow the labeling of commodities as being "organic."

Q. WHAT IS THE SIGNIFICANCE OF THE FACT THAT THE NATIONAL ORGANIC PROGRAM DOES NOT SPECIFY ANY THRESHOLD OR MAXIMUM WITH RESPECT TO ADVENTITIOUS PRESENCE OF GM MATERIALS IN ORGANIC PRODUCTS?

A. The National Organic Program ("NOP") is a process-based marketing program, established by USDA and maintained by USDA-approved certifiers. It audits and certifies that procedures consistent with the program's rules are employed in organic crop production. It does not specify the quality or purity of the final product. For example, the NOP recognizes that very low levels of pesticides excluded in organic production may occur on organic products due to drift from neighboring farms and establishes maximum thresholds for this inadvertent occurrence, if it is present. In an environment in which only 2% of agricultural production is certified organic, low levels of those excluded pesticides that are widely used in conventional agriculture should not disrupt normal marketing of organic products. The use of GM seed varieties for crop production is excluded by the National Organic Program, but the rules do not prohibit the inadvertent presence of GM-derived material. On its website, the NOP states, "The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of

the products of excluded methods will not affect the status of the organic operation. As to the status of the commodity, USDA's position is that this is left to the buyer and seller to resolve in the marketplace through their contractual relationship." (http://www.ams.usda.gov/nop/Q&A.html#Production/Handling, posted 1/14/05.) Thus, organic producers do not lose certification simply due to adventitious presence of GM material.

Q. DO YOU HAVE ANY FURTHER TESTIMONY?

A. No, that's all.

Thank you.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 23rd day of March 2007 at Davis, California.

/s/

KENT J. BRADFORD

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/

B. ANDREW BROWN

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	No.: C 06-01075 CRB **DIRECT TESTIMONY OF TIMOTHY J. NANTELL REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courthouse 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. My name is Timothy J. Nantell. My business address is 3-093 Carlson School of Management, 321 19th Avenue South, Minneapolis, Minnesota 55455.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am a professor of finance at the Carlson School of Management at the University of Minnesota.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I joined the University of Minnesota in 1980, having been on the faculty at the University of Michigan from 1971 through 1980. I received my Ph.D. in Finance from the University of Wisconsin in 1971. I also was awarded the Masters of Business Administration in Finance from the University of Wisconsin. From 1987 through 1991, I served as Associate Dean of Faculty Affairs and as Acting Dean of the Carlson School of Management at the University of Minnesota. In those positions, I was responsible for developing and delivering an annual $25 million operating budget. I returned to my position as a professor of finance in 1992, and served as the Chair of the Finance Department at the Carlson School from 1995 to 1999. I served as the Faculty Director for MBA programs from 1999 to 2001 and Associate Dean for MBA Programs for 2001 to 2002. I co-founded the Carlson Funds Enterprise in 1997. Carlson Funds Enterprise is an educational LLC training graduate students as security analysts by having them manage $20 million of actual clients' money. In conjunction with another professional faculty member, I oversee this enterprise, both its educational and operational aspects.

I have published various books and articles and software programs in a variety of areas related to economics and finance and am also the author of numerous papers in the field. My research,

teaching and consulting activities have included corporate, project and security valuations and financing for a variety of businesses. These activities have for some years been centered on issues regarding the analysis of profits and lost profits and the valuation of securities, businesses and business opportunities. I have served as a consultant for small, medium and large firms on issues ranging from valuation issues, including the valuation of patents, to financing issues, to mergers and acquisitions. These firms have included those that participate in the agricultural production marketplace. I have also provided executive education classes through the University as well as directly to private firms.

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. The purpose of my testimony is to calculate the impacts that would occur to Forage Genetics, Inc., seed growers, seed companies. seed dealers and distributors, and forage growers from an injunction prohibiting the continued planting and sale of Roundup Ready alfalfa pending the completion of an Environmental Impact Statement by APHIS.

Q. PLEASE PROVIDE A SUMMARY OF THE METHODOLOGY USED TO CALCULATE THESE DAMAGES.

A. I have identified the impact that the injunction would have on the planting and harvesting of acres used to grow RRA seed, the number of pounds of RRA seed growers by the seed growers and purchased by FGI, the amount of RRA seed purchased and sold through the supply chain

(including amounts that would be lost or inventoried due to the injunction), the amount of RRA seed purchased by forage growers, and the number of acres of RRA forage planted and used or sold by the forage growers. I have assumed that all parties would mitigate the impact of the injunction by growing or selling non-RRA substitute crops and seeds. and that all parties would, after the assumed two year length of the injunction, extremely aggressively move toward bringing RRA volumes back as quickly as possibly to where they would have been absent the injunction. Then, based on historical prices and costs, forecasts, surveys, contracts, and discussions with FGI personnel, I have translated all of this information into the dollar impact that the injunction would have on the contribution to overhead for each of the participants in the production and sales chain.

Q. WHAT ASSUMPTION HAVE YOU MADE REGARDING THE PERIOD OF TIME REQUIRED FOR PREPARATION OF AN EIS?

A. I have assumed that seed and forage growers will be able to resume planting in the fall of 2009.

Q. PLEASE PROVIDE A SUMMARY OF THE RESULTS OF YOUR ANALYSIS.

A. My analysis shows the injunction will have the following cumulative negative impacts:

Seed Growers:	($ 4,500,000)
FGI:	($ 6,750,000)
Seed Companies:	($ 4,550,000)
Seed Distributors/Dealers:	($ 4,300,000)
Forage Growers:	($205,000,000)

These impacts are after mitigation and assume extremely aggressive efforts to get RRA volumes back as quickly as possible to where they would have been absent the injunction—yet the impact is still ($225,000,000) in the aggregate.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this _th day of March 2007 at Minneapolis, Minnesota.

/S/ Timothy Nantell

TIMOTHY J. NANTELL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants. and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB **DIRECT TESTIMONY OF DANIEL H. PUTNAM REGARDING PERMANENT RELIEF** DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. My name is Daniel H. Putnam. My business address is Department of Plant Sciences, One Shields Avenue, University of California, Davis, California 95616-8515.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am a Cooperative Extension Specialist and Agronomist in the Agriculture Experiment Station with a specialty in Alfalfa and Forage Crops in the

Department of Plant Sciences at the University of California, Davis, California.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I am an agronomist (crop production scientist) with a Ph.D. in Plant and Soil Science, with over 27 years experience with field crops and field crop research. As state-wide Alfalfa Specialist and Faculty at the University of California, Davis, I work full time on research and extension with alfalfa. I work with farmers, both organic and conventional, seed companies, supply companies, public agencies, and anyone interested in forages. I am chair of the UC California Alfalfa & Forage Workgroup, a collection of about twenty UC scientists with expertise on alfalfa. I am Secretary of the California Alfalfa & Forage Association (representative grower group), the University liaison with the CA Farm Bureau Federation, a board member of the National Alfalfa & Forage Alliance, a board member of the national Alfalfa Variety Review Board, board member of the Certified Crop Advisor Program, and a member of the board of the National Forage Testing Association. I have over 100 research and extension papers related to alfalfa and forages. I guess it would be safe to say that my life is steeped in issues related to alfalfa and forage crops. A copy of my curriculum vitae is attached as Exhibit A.

Alfalfa is California's largest acreage crop, and I am frequently asked to provide un-biased science-based information about new varieties, new pesticides, organic methods, fertilizers, new forage crops, seed treatments, forage quality lab analysis,

economics, irrigation practices, water quality, wildlife impacts, and the whole range of production practices and technologies which impact alfalfa crop production.

Nearly all of these technologies and public issues have supporters and detractors, and entities (businesses, public agencies, advocacy groups) that may champion or dislike those practices. For example, one seed company champions their variety, and another seed company their variety, one organic fertilizer company has a product which competes with another. Regulatory agencies, environmental groups, agricultural chemical companies, and growers may differ (okay, they do differ) on their view of pesticide use and environmental impacts. The University of California, and myself as Alfalfa Specialist, are continually called upon to provide non-biased science-based information to address these sometimes controversial issues.

We are sometimes faced with the challenging role of informing growers of the scientific evidence that their cropping practices may impact the environment, for example the presence of herbicides or pesticides in ground or surface water. For example, we have measured organophosphate insecticides appearing in water from alfalfa fields, and have published this data and informed both growers and regulators, and advised growers of methods to avoid this. We do not wish to win popularity contests. Our role in UC Cooperative Extension is to provide unbiased information about a wide range of issues, regardless of the interests of different parties and their views on particular

issues (whether large corporations, public agencies, private advocates, or growers).

Q. WHAT IS YOUR EXPERIENCE RELATING SPECIFICALLY TO ROUNDUP READY ALFALFA?

A. My colleagues and I have been researching the Roundup Ready trait in alfalfa and its potential for the past seven years, through our own field trials, and a thorough discussion and analysis with colleagues and growers of its potential impacts and role in the environment and in the market. This resulted in the publication of the peer-reviewed document "Roundup Ready Alfalfa: An Emerging Technology" (University of California of Agriculture and Natural Resources Publication 8153, 2004 http://anrcatalog.ucdavis.edu/pdf/8153.pdf) (Exhibit B), where we presented our field research findings and outlined the positive and negative features of the Roundup Ready technology, so that growers and seed companies (and public groups) could make informed decisions about it. This was published well over a year before deregulation of Roundup Ready alfalfa.

More recently, I have studied the issue of the potential for coexistence of Genetically Engineered (GE) and non-GE alfalfa, including organic alfalfa. I have written articles which 1) evaluate the sensitivity and concerns of portions of the alfalfa hay industry to genetically engineered organisms, particularly organic and export growers, and 2) describe simple steps that would enable neighbors who practice different forms of agriculture to successfully coexist. I presented these ideas to grower meetings in Visalia, California in 2005: "Market Sensitivities and Methods to Assure

Tolerance of Biotech and Non-Biotech Alfalfa Production Systems" (see http://ucanr.org/alf_symp/2005 /05-279.pdf) (Exhibit C) and later in a peer-reviewed article: "Methods to Enable Coexistence of Diverse Cropping Systems Involving Genetically Engineered Alfalfa" (University of California Agriculture and Natural Resources Publication 8193, 2006 http://anrcatalog.ucdavis.edu/pdf /8193.pdf) (Exhibit D).

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. My testimony will address several issues raised by the Court in its February 13, 2007 Memorandum and Order. The crux of this ruling centered upon concerns that the planting of Roundup Ready alfalfa would potentially harm organic and other growers who did not wish to have this trait in their fields. Additionally, concerns over the dangers of weed resistance were raised. I will address these issues here, based upon my professional knowledge and experience as a full-time state-wide specialist with expertise on alfalfa.

II. THE ALFALFA MARKET

Q. PLEASE PROVIDE A BRIEF DESCRIPTION OF THE ALFALFA MARKET IN THE UNITED STATES.

A. Over 22 million acres of alfalfa hay are harvested in the United States each year, with the largest alfalfa-producing states in the Midwest and West, particularly California, South Dakota, Wisconsin, Idaho, Minnesota, and Iowa. The vast majority of this alfalfa is grown for domestic dairies, with important but minority consumption by horses, beef, sheep and goats. Less than 1% of this

acreage is devoted to organic alfalfa (it is actually probably less than 0.5% by volume, but growing), and approximately 1% nationally devoted to export, by volume, although export is more important in certain areas. For example, exports are particularly important in Western States, such as the Imperial Valley of California and Central Washington, where exports make up a larger percent of production. However, the key U.S. markets are domestic; alfalfa hay is considered a staple of U.S. dairy production, and dairy is clearly the driving force for U.S. alfalfa production.

Q. HOW MUCH OF THE ALFALFA MARKET WILL BE SENSITIVE TO GE TRAITS?

A. The vast majority of alfalfa is grown for uses or markets that are not highly sensitive to the presence of GE traits. The primary markets sensitive to the GE trait in alfalfa are export markets, organic markets for dairy and beef, and some hay grown for horses. I have estimated that these "GE-sensitive" portions of the alfalfa market make up between 3 and 5% of the U.S. market. To date, I have no reason to change these estimates, although the sensitivity varies significantly between regions, viewpoints of growers, and markets, and may change over time. Of the 'GE-sensitive' grower, export growers are more important than organic alfalfa hay growers by volume. This is important since the 'level of tolerance' may be different for these two groups. But regardless of the minority status of these growers, it is important to assure that they not be unduly affected by their neighbors' decisions or the public release of this technology.

If I truly believed that the introduction of Roundup Ready alfalfa would harm these growers, or present significant and immediate environmental threats I would say so, and loudly. We have a duty as University scientists to address public concerns over water quality, air quality, and the environmental impacts of agriculture, including unwanted effects on organic growers or other grower's markets.

III. COEXISTENCE

Q. DO YOU BELIEVE THAT THE CONTINUED PLANTING OF ROUNDUP READY ALFALFA PENDING THE COMPLETION OF AN ENVIRONMENTAL IMPACT STATEMENT WILL HARM ORGANIC OR OTHER GE-SENSITIVE GROWERS?

A. No, I do not believe that the continued planting of Roundup Ready alfalfa while APHIS completes a more thorough review will harm organic or other GE-sensitive alfalfa hay growers for the following reasons:

(1) The probability of gene flow between alfalfa hay crops in close proximity is near zero, as I explain below.

(2) Growers using different methods of production than neighbors (e.g. conventional and organic) have been able to resolve their differences using ordinary methods, and this technology is no different in either scope or potential impact than these other technologies.

(3) There are simple practical methods available to prevent or reduce the probability of unwanted gene flow even further between neighboring hay fields that are not extraordinary in nature. These

methods are illustrated below and in my attached papers.

(4) Weed resistance, which is cited in the Court's February 13 Order, is a long-term issue associated with all herbicide use, is not unique to Roundup (nor linked per-se to Roundup Ready crops) and will not be substantially affected by the continued planting of Roundup Ready alfalfa during the period of the EIS reevaluation.

(5) There are inexpensive testing methods available to organic and other GE-sensitive growers who wish to provide added levels of market assurance to their customers, which should negate any effect driven by perception of their customers due to the planting of Roundup Ready alfalfa in their neighborhoods.

(6) Since the introduction of Roundup Ready alfalfa in August 2001, the organic or other GE-sensitive markets have not been hurt—on the contrary, the demand for organic hay has soared over the past two years.

To put this matter more succinctly: If an organic grower (or a grower otherwise 'sensitive' to the GE trait), plants non-GE seed for hay production near to Roundup Ready alfalfa hay fields, that grower should be nearly 100% assured of continuing to harvest non-Roundup Ready forage for the life of the alfalfa stand, unless highly unusual circumstances prevail. These unusual circumstances can be prevented with a few simple management practices.

Q. WHAT IS THE PROBABILITY OF GENE FLOW IN ALFALFA HAY CROPS?

A. There is no evidence to date of any contamination of organic or conventional hay fields originating from Roundup Ready hay fields, and the available scientific evidence demonstrates that the risk of such contamination is almost zero.

Alfalfa requires pollinators for maximum seed production, and genes flow from plant to plant in the normal course of seed production. Thus, some pollen may flow from one seed field to a closely neighboring seed field, although even in seed fields, this amount is small. Currently, gene flow studies have shown that in closely situated alfalfa seed fields, the level of gene flow is measured to be 1.5% at 900 feet with honeybees and 1.5% at 500 feet with leafcutter bees as pollinators. Remember that this is under conditions that maximize gene flow (pollinators are present, simultaneous flowering, seed is allowed to mature, etc.) for both a target and source plots (see Exhibit B, "Roundup Ready Alfalfa, an Emerging Technology," University of California Agriculture and Natural Resources Publication 8153, 2004 http://anrcatalog.ucdavis.edu/pdf/8153.pdf).

More recent studies (2006) by Dr. Larry Teuber at UC Davis have found a potential for approximately 0.25% gene flow from a blooming alfalfa hay field to an alfalfa seed crop at 165 feet and gene flow was rarely detected (0.00 to 0.05%) at distances greater than 350 feet from the source (Teuber and Fitzpatrick, California Seed Symposium Proceedings, February, 2007). This is under circumstances where pollen would flow from a source Roundup Ready hay crop that was allowed

to flower to 20% bloom to a target seed crop, and the seed harvested and tested.

The potential for gene flow in alfalfa grown for hay is not the same as that for alfalfa grown for seed because of very different production methods. Therefore these studies, particularly the latter one, illustrates a 'worse case scenario' for hay fields, since conditions (in the case of seed-seed) were maximized for gene flow, and (in the case of hay-seed) at gene flow was encouraged by allowing full seed production and seed harvest in one of the crops.

Gene flow from hay crop to hay crop will likely be many orders of magnitude lower than this amount, since these conditions which maximize gene flow are rare in alfalfa hay production. All of the standard practices in alfalfa hay production work against gene flow. We cut early (usually before flowering) to achieve good quality, so that flowering is not maximized. We don't deliberately add honeybees or leafcutter bees, which in any event prefer other species, so that pollination and pollen movement is not maximized. We do not allow seed to develop under normal circumstances to any significant degree since we cut early. The rare seed that is developed is almost always and completely removed with the crop. The occasional rare seed that does develop, remain, and drop to the ground does not readily germinate and grow in the vigorous canopy of an alfalfa field, as any grower who has tried to seed alfalfa into an existing stand will attest. If any level of probability is applied less than 100% for each of these 'environmental filters' to gene flow in alfalfa

fields, the probabilities of gene flow would be many orders of magnitude less than the 0.25% AP, the 'worse case scenario' for hay-to-hay gene flow. We should remember, also, that this is considering closely-situation hay fields. As the distance between hay fields increases, the probabilities become even lower.

Q. CAN YOU ESTIMATE THE PROBABILITY OF GENE FLOW FROM ALFALFA HAY TO ALFALFA HAY?

A. The exact probabilities of these environmental filters which prevent gene flow are unknown, but can be projected, using some reasonable assumptions. We start with the 'worse case scenario' or maximum probability of Adventitious Presence from hay to seed as 0.25% at 165 feet, which is the AP from a harvested seed crop at 165 feet from a hay field harvested at 20% bloom. We must remember that this is a situation where seed production is optimized for one of the crops (seeds allowed to mature, pollinators added, etc.), and the seed harvested and measured. If each of these steps are given, for example, the probability of 10% or 1 out of ten, the mathematics would be as follows:

1. If the probability of Simultaneous Flowering between two fields is 1/10 (10%), this lowers the probability of gene flow from 0.25% to 0.025% AP at 165 feet.

2. If the probability of Sufficient Pollinator Activity creating conditions for gene movement is 1/10 (10%), the probability becomes 0.0025% AP at 165 feet.

3. If the probability that Embryos are given sufficient time to be formed, and that seed matures

(this typically takes more than a month after flowering) is 1/10 (10%), the probability of gene flow would then be 0.00025% AP at 165 feet.

4. If the probability that mature seed remains in the field and is not removed by hay harvest is 1/10 (10%), the probability of gene flow would then be 0.000025% AP at 165 feet.

5. If the probability that seed germinates, grows, and isn't out-competed by the existing crop is 1/10 (10%), the probability of gene flow would then be 0.0000025% AP at 165 feet.

Thus, in this projection, the probability that pollen from a neighboring GE hay field will contaminate a neighboring organic or otherwise GE-sensitive hay field is 0.0000025%, or 2.5 out of 1 million AP.

I want to clarify that these probabilities cannot be known with great certainty, and will be affected by individual environmental circumstances—however, this does not change the validity of the argument. It would only change the probabilities from very, very, very, very low, to very, very, very low AP in hay crops.

For example, in the above projection, I have used an arbitrary percentage of 10%. However, several of these 'environmental filters' are likely to create greater or lesser probabilities. For example, the probability of two fields flowering simultaneously might be greater than 10%, if weather patterns prevent two neighboring farmers from harvesting their crops in time. However, the probability of gene flow through some of the other 'environmental filters' is likely to be far less than 10%. For example, the probability that seed is actually produced from flowers that might be

blooming during a hay production period is likely to be closer to 1 out of 1,000 or even 1 out of 10,000 (e.g. out of 1,000 or 10,000 flowers, fewer than 1 seed is likely to be produced—this is much closer to reality than 10%, since hay is almost always harvested before seed is produced). Similarly, if a rare seed is produced, the chances of that seed remaining in the field might be closer to 1%, since the foliage (along with the seed) is almost always completely removed (e.g. out of 100 of these unusual seeds in a field, only one might remain). We have observed that the probability of seed falling to the ground, germinating and surviving the intense competition of an existing alfalfa field to be established so that it contributes to the subsequent hay crop is probably less than 1% (e.g. less than one of 100 seeds that falls to the surface of the ground will actually germinate on the surface and survive competition so that a plant is produced).

If we assume a probability of simultaneous flowering at 100% and of pollinators present sufficient quantities for gene movement at 100% (items 1 and 2 above), but ascribe a probability of 1% to the other environmental filters of seed set, seed retention and seed recruitment, the probability of gene movement would then be projected to be 0.00000025% of the hay would contain adventitious presence at 165 feet based upon these assumptions (this is 0.25 in 1 million). In either scenario, the potential level of 'contamination' or adventitious presence is very very very low, essentially near zero, as it was in the previous projection. We should remember

also, that these are estimates for crops at close proximity (165 feet), and our evidence shows that as this distance increases, the numbers become even lower

Q. WILL THESE NEAR ZERO LEVELS OF GENE FLOW HARM ORGANIC OR GE-SENSITIVE GROWERS?

A. No, this level of risk should not harm or otherwise threaten a GE-sensitive grower for the following reasons: (1) the level of risk is likely to be far less, and certainly no greater than, the risk of any other practice that might affect neighbors, as discussed below; (2) an expectation of absolutely zero risk from neighbors does not exist in practice for any technology; (3) there are simple practical methods to lower this level of risk even further, and (4) this level of potential adventitious presence is so low that it should not have an effect on the marketing of organic or otherwise GE-sensitive hay. Specifically, National Organic Program certification standards are process based and do not include any specific tolerance levels for biotech traits. (See http://www.ams.usda.gov/nop/Q&A.html#Production/Handling)

The potential effects on neighbors who grow GE-sensitive crops appear to be a key component of the preliminary injunction in this case. An injunction preventing future plantings of Roundup Ready alfalfa, however, is not warranted. Those familiar with farming practices would estimate that the potential for GE movement in from alfalfa hay crop to alfalfa hay crop (0.25 per million) is far less than many other practices that might impact neighbors. For example, neighbors that use legal pesticides near to an organic farm (or near farmers

growing crops sensitive to an herbicide) need to prevent unwanted movement of pesticides onto their neighbors. Herbicide drift is a very real risk of influence of one farmer upon another, and the probability of herbicide drift is much greater than the potential for GE gene movement in hay crops, especially in hay fields 165 feet apart. Those farmers fertilizing near a neighbor's field need to prevent the movement of fertilizer from moving onto a neighbor's field. Whether it is an insecticide or herbicide spray, the accidental dropping of fungicide-treated seed from an airplane, or the movement of fertilizer, growers must prevent these conventional techniques from impacting their neighbors, particularly organic growers where their livelihood depends upon excluding these practices. These possibilities are common in agriculture and the possibility of GE movement from hay to hay (e.g. 0.25 per million) is far less than many of these possibilities.

Lest we make the mistake of imagining that this is only the effect of a conventional grower impacting an organic grower—the opposite might also be true. Organic practices are not risk free. Manures can run off organic farms and affect neighbors' waterways and fields. Weeds can be allowed to flourish if not controlled properly on organic farms, and weed seed blown onto neighbors' fields, even poisonous weeds that kill livestock or noxious weeds that spread. Uncontrolled insect pests on farms (including organic farms) can negatively impact their neighbor's crops, causing them harm. Tillage, a common organic technique, can cause sediment to run off and impact neighbors or public

waterways. Good organic growers know how to address these issues, and any potential impacts are usually successfully resolved between neighbors or through utilizing good practices, whether organic or conventional.

Neighbor effects are ordinary aspects of farming and do not require extraordinary measures. Whether it is over-sprays affecting neighbor's crops, fertilizers which run off from conventional fields, or uncontrolled insects or manures which may affect one's neighbors from organic fields, or the small (0.25 per million) likelihood of GE movement, it is the common responsibility of neighbors to resolve these issues, which are common occurrences in farming communities and neighborly relations.

Q. WHAT PRACTICES CAN BE USED TO ALLOW GE AND NON-GE ALFALFA VARIETIES TO COEXIST?

A. In my paper on "Coexistence," (attached as Exhibit D), I have outlined the methods to further prevent cross-contamination for growers producing organic or for GE-sensitive hay markets. The most important of these is the choice and testing of non-GE seed at planting (which is the most likely way of AP entering a hay field). Other techniques include eliminating feral (or unharvested) alfalfa, watching and staggering flowering of neighboring fields through harvest schedules, harvesting before excessive bloom (desirable anyway for good hay production), identification of hay lots (which organic and export growers must do for the most part anyway), and testing (if necessary) to assure buyers of the non-GE status of their crop.

Q. DOES THE POSSIBILITY OF GENE TRANSFER POSE ANY RISKS TO HUMANS OR ANIMALS?

A. Roundup Ready alfalfa is not a toxin, unlike some pesticides, which are toxic at certain levels. This is a technology that has been found by FDA to be safe to feed 100% to animals through research trials, and now millions of farm animals have been fed corn, soybean, and now alfalfa with the Roundup Ready gene inserted. There is no scientific evidence that suggests any negative impact of the Roundup Ready gene on animal production. It should be noted that the same, sadly, cannot be said of weedy alfalfa fields which kill animals every year, a condition that the Roundup Ready alfalfa technology can correct. To summarize, if low levels of AP are present in otherwise non-GE hay, it would not reasonably pose a genuine risk to farm animals or to humans. In fact, the Roundup Ready gene cannot even be detected in animal products such as beef or milk.

Q. WOULD THE VERY SMALL POSSIBILITY OF AP CALCULATED ABOVE HARM THE MARKETS OF ORGANIC GROWERS OR EXPORT GROWERS, THE MAJOR GE-SENSITIVE GROUPS?

A. No. Additionally, there are inexpensive methods available to assure customers of the absence of the Roundup Ready trait. We have conducted research on 'test strips' which have the capability of detecting AP in hay crops with various mixtures of Roundup Ready and non-Roundup Ready hay (data unpublished). In field studies with hay harvested from mixtures of 0%, 1%, 5%, and 10% Roundup Ready, the test strips always produced positive readings at 1%, 5%, and 10%, and gave

negative ratings at 0%, when tested by three individuals in three separate states in blind tests. Thus, these test strips should provide a useful tool in assuring markets of the non-GE nature of a hay crop. Using these tests should enable growers to confirm the absence of GE traits in their hays destined for sensitive markets and provide assurances to buyers as to the stewardship of non-GE hay. These tests strips are routinely used by some alfalfa hay exporters today.

Moreover, given that the tolerance (requirements for labeling) for GE traits in food crops in Japan is 5% and 0.9% in Europe, the very small probabilities described above for AP in hay (animal feed) crops should not normally present difficulties for buyers of non-GE hay. For organic producers, the very small potential for AP should not ordinarily present significant worries for their markets because the probability of gene flow and adventitious presence is extremely low.

In contrast to claims that Roundup Ready alfalfa may harm the organic market, ironically, the introduction of Roundup Ready alfalfa might actually strengthen the market for organic hay, since market distinctions might be heightened in those members of the public who are philosophically opposed to GE crops. Evidence to date supports that view, since demand for non-GE hay has increased significantly over the past two years—at a very minimum, it cannot be said that the introduction of Roundup Ready alfalfa has damaged the demand for organic hay since its commercialization in 2005.

IV. BENEFITS OF ROUNDUP READY ALFALFA

Q. IN GENERAL, WHAT ARE THE BENEFITS AND DRAWBACKS OF ROUNDUP READY ALFALFA?

A. The positive features of this technology include very flexible and effective broad-spectrum weed control, the capability to simply produce weed-free hay which benefits animal health and milk production, and environmental benefits due to the replacement of herbicides which have been shown to impact water quality. We also anticipate stands to last longer. The principle drawbacks are the lack of residual (long term) weed control, the possibility of weed shifts or weed resistance if proper stewardship is not followed (although as noted, this a universal issue with all herbicide use and is not unique to Roundup Ready alfalfa), and consumer acceptance of GE technology (see Exhibit B, "Roundup Ready Alfalfa: An Emerging Technology" for details of these features).

Q. WOULD THERE BE HARM IN PREVENTING PLANTING OF ROUNDUP READY ALFALFA WHILE USDA-APHIS STUDIES THE ENVIRONMENTAL IMPACTS?

A. A preemptive ban on further plantings would prevent the immediate environmental benefits of this technology from being realized by growers and the public. There are thousands of alfalfa growers who have planted this technology because they believe that it provides tremendous advantages in providing higher quality hay and superior weed control strategies for problem weeds. There are important noxious and difficult weeds that growers have been historically unable to control, including perennial weeds that infest fields in large measure,

and stubborn and poisonous weeds which lower the value of the crop. This technology has the potential of preventing animal deaths due to poisonous weeds, and preventing spread of noxious weeds. Growers have chosen this technology in greater numbers than expected in spite of the increase in seed price (about double that of conventional seed) and the necessity of signing technology agreements. They have done so due to the tremendous advantages in simplicity of control and the prospects of producing weed-free hay.

I would contend that, if impartial entities examine the evidence leaving aside opinions as to whether one likes GE technology or not, the Roundup Ready technology, in balance, has a range of environmental benefits that are superior to current technologies.

Q. WHAT ARE THESE ENVIRONMENTAL AND PUBLIC BENEFITS?

A. Animal Health. About two years ago, there was an incident in California where over 60 dairy cows were killed when fed a crop of alfalfa. The alfalfa itself did not harm the animals, but the crop was heavily infested with weed 'lambsquarters' and other weeds which accumulated high levels of nitrate, since the crop was produced on a heavily organic soil. The nitrates killed the animals, which could have been prevented with effective weed control, including Roundup Ready alfalfa. This is not an unusual occurrence, nor a trivial one. Each year, the UC Davis Veterinary diagnostic laboratory treats hundreds of sickened animals and many who die of the effects of poisonous weeds

such as fiddleneck, common groundsel, or nitrates in weeds.

Although no evidence of harm to animal health from Roundup Ready alfalfa has been shown, the real risk of failure to control weeds has been demonstrated to be very real and very lethal in many cases every single year. Many times, growers are simply unable to control weeds with conventional or organic methods, and thus have had to accept weedy, sometimes poisonous, hay crops. The Roundup Ready technology offers a simple solution which, since it has higher flexibility and effectiveness, will, in balance, benefit animal well-being.

Water Quality. A group of UC scientists (including myself) have been investigating the source of winter-applied alfalfa herbicides which were found by the state Department of Pesticide Regulation (DPR) in drinking wells in California's Central Valley. We traced the methods by which these herbicides seeped into the wells, and the DPR has placed restrictions on the use of these herbicides for sensitive soils, as a result. This is a real environmental hazard of current technology, for which there are practical solutions. The Roundup Ready technology offers a solution for farmers in these sensitive areas, since glyphosate is of minor concern to water quality regulators, due to its lack of persistence, lack of toxicity, and lack of solubility, whereas existing herbicides are of concern for water quality. The Roundup Ready technology offers a very real solution to several water quality problems that face agriculture. If this technology were banned for the next few

years, the public benefit of improved water quality for those regions would be lost.

No-till systems. One of the important benefits of the Roundup Ready technology is the adaptation of Roundup Ready alfalfa to no-till systems. No-till or minimum till reduces the energy requirements of agriculture. The Roundup Ready technology may allow fewer trips across the field during stand establishment, and save soils that are ordinarily lost through tillage and soil erosion. If growers are not permitted to use the Roundup Ready technology, tillage must be relied on for stand establishment. The ability of the Roundup Ready technology to easily control weeds in no-till systems is an important public benefit.

Forage Quality and Dairy Production and Profitability. One of the principle values of the Roundup Ready alfalfa technology is the ability to more easily produce high quality alfalfa. Higher quality, weed-free alfalfa (especially free of poisonous weeds) leads to greater milk production and profitability. If growers did not expect this to be the case, they would not purchase the technology. Those growers with significant weed control problems have been very interested in adapting this weed control technology to prevent degradation (of quality and economic value) of their crop. Weeds are an important quality limiting factor for alfalfa, and high weed content leads to lower milk production.

* * *

Q. HAVE YOU REVIEWED THE JUDGMENT PROPOSED BY THE FEDERAL DEFENDANTS IN THIS CASE?

A. Yes.

Q. IN YOUR OPINION, ARE THE MEASURES SUGGESTED BY THE GOVERNMENT SUFFICIENT TO PROTECT THE INTERESTS OF GE-SENSITIVE GROWERS AND CONSUMERS, PRESERVE NON-GE ALFALFA, AND MINIMIZE THE RISK OF AP PENDING COMPLETION OF THE EIS?

A. The measures proposed by the government are appropriate to prevent any harm to GE-sensitive growers and consumers from the risk of AP from Roundup Ready alfalfa seed production, which poses the greatest risk of AP in organic or conventional hay. In addition, hay growers should follow the recommended practices outlined in my paper "Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa," cited above and attached as Exhibit D, to prevent AP from Roundup Ready alfalfa hay production to organic or conventional alfalfa hay. Such practices include managing hay fields to minimize flowering, seed production, and volunteer plants and taking steps to control feral alfalfa. Steps for market assurance, such as use of the test strips, are available to prevent harm to GE-sensitive markets.

V. CONCLUSION

Q. DO YOU HAVE ANY CONCLUDING THOUGHTS?

A. I do not believe an injunction is necessary for the protection of organic or other GE-sensitive growers from the continued planting of Roundup-Ready alfalfa while the Environmental Impact Study is completed. Methods are available to assure neighborly coexistence to control gene flow between hay fields, just as methods are in place to

prevent any other potential influence of neighbor upon neighbor from any technology used for hay production. The immediate benefits to growers and the public from the adaptation of the Roundup Ready technology for those difficult-to-control, poisonous, and deadly weeds which can cause death of animals, and the benefits for water quality would be lost if growers could not continue to plant Roundup Ready varieties during the period of full environmental review.

Q. DOES THIS CONCLUDE YOUR TESTIMONY?

A. Yes, it does.

Thank you.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this _23_ day of March 2007 at Davis, California.

/s/
DANIEL H. PUTNAM

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled document.

/s/
B. ANDREW BROWN

[Exhibit A]

Curriculum Vitae

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Education:

1986 Ph.D. (Plant and Soil Sciences), University of Massachusetts, Amherst

1983 M.S. (Plant and Soil Sciences), University of Massachusetts, Amherst

1977 B.S. (Agronomy), Wilmington College, Wilmington, Ohio

Employment History:

1993-present	Cooperative Extension Specialist and Agronomist in the Agriculture Experiment Station—Alfalfa and forage crops, University of California, Davis, California
1986-1993	Assistant Professor, University of Minnesota, St. Paul, Minnesota. Specialist in New and Alternative Crops.
1985-1986	Research Associate, University of Massachusetts, Amherst, Massachusetts.

Current Position Description:

Cooperative Extension Specialist and Experiment Station Scientist at UC Davis for alfalfa and forage cropping systems, and Chair, UC Alfalfa Workgroup. This position entails statewide responsibility for extension and research activities related to alfalfa and forage crops. Forages occupy about 1.8 million acres in California, the most prominent of which is alfalfa, worth about $1 billion/year. Conducts educational activities (field days, symposia, newsletters, websites) pertaining to forage crops. Conducts field and laboratory research related to alfalfa and harvested forage crops. Works closely with CE Farm Advisors in the counties, with UC scientists, and with the alfalfa industry in California. Currently chair of the California Alfalfa Symposium, and past president of the National Forage Testing Association. Other interests include introduction of new crop species, crop ecology, and forage quality analysis methods.

Research Interests:

Alfalfa cultivar interactions with agronomic practices, economics of the cutting schedules and the yield-quality tradeoff in alfalfa, forage quality analysis methods, irrigation techniques, alternative forage crops, interactions of alfalfa and the environment.

Honors, Awards:

1984-85 - Fulbright Scholarship for overseas study (India).

1999 - Hilgaard Award for Outstanding Teaching-Extension Specialist. California Association of Farm Advisors and Specialists.

2000 - Award for Excellence - American Society of Agronomy Extension Publications Award - Newsletter category, (California Alfalfa & Forage Review, candidate is editor)

2000 - Extension Education Award - National Association of Farm Advisors and Specialists
2000 - Achievement Award - California Associations of Farm Advisors and Specialists

Industry, Professional Memberships

Chair, UC California Alfalfa Workgroup
Chair, California Hay Testing Consortium
Chair, California Alfalfa Symposium
President, National Forage Testing Association
California Alfalfa & Forage Association founding board member and Secretary
American Society of Agronomy
Crop Science Society of America
California Farm Bureau Federation, Hay Advisory Committee, UC Liaison
Alfalfa Council (national), Advisory Board
National Alfalfa Intensive Training Seminar Instructor

Consulting:

I have consulted with USDA oversees development projects, World Bank Oilseed Project, with private parties in Egypt, Saudi Arabia, Pakistan, China, and India. I have also consulted on subjects related to forage production, hay storage and marketing, spontaneous combustion of hay, hay quality, and the use of forages for mitigation of pollution including applications of effluent and industrial wastes. I have traveled overseas for scientific exchanges to Chile, Russia, India, Poland, and Egypt.

Partial List of Publications

(This is a partial list which includes samples of peer-reviewed (*), proceedings papers and extension articles– a complete list of publications available by contacting Dr. Putnam):

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AGRICULTURAL BIOTECHNOLOGY IN CALIFORNIA SERIES Publication 8153

Roundup Ready Alfalfa: An Emerging Technology

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INTRODUCTION

Glyphosate-resistant crops, also known as "Roundup Ready" (RR), have become an important part of cropping systems in the United States. In 2004, approximately 13 percent of corn, 85 percent of soybean, and 60 percent of cotton acreage was occupied by RR varieties. Alfalfa (*Medicago sativa*) is the nation's third most important crop in economic value, and it occupies more than 22 million acres (8.9 million

ha) in the United States (USDA 2004). It is considered the premier forage crop. It is the primary feed for dairy production, and is commonly fed to beef cattle, sheep, and horses. Alfalfa is also used for greenchop and silage in many areas. California is the leading producer of alfalfa hay in the United States, followed by Wisconsin, South Dakota, Minnesota, and Idaho. Roundup Ready technology has been successfully incorporated into alfalfa and is scheduled for commercial release in 2005. This publication reviews the important attributes and issues pertaining to RR technology as applied to alfalfa and the potential impacts of this technology on production systems and markets.

What Is Roundup Ready Alfalfa?

Roundup (glyphosate) is a broad-spectrum herbicide that kills a wide range of plants. It is not normally applied directly to crops. The RR technology incorporates genetic resistance to glyphosate into crop plants by inserting a single bacterial gene that modifies 5-enolpyruvylshikimate-3-phosphate (EPSP) synthase, an enzyme essential for plant growth. Monsanto has used this technology to develop several RR crops (e.g., cotton, soybeans, and corn).

Roundup Ready technology will enable the development of new weed control strategies for alfalfa. Specifically, these new varieties will allow glyphosate (for example, Roundup UltraMax—see label for the full spectrum of weeds controlled and application specifications) to be applied over the top of the entire crop to control a wide spectrum of annual and perennial weeds commonly found in alfalfa. Several of these weeds, especially perennials, are difficult to control using conventional herbicides or nonherbicide weed

control methods. Although scientists at Monsanto and Forage Genetics International have developed the technology, RR alfalfa varieties will be marketed broadly by a wide range of seed companies. Important characteristics, such as genetic resistance to insects and diseases and yield potential, remain important criteria for selecting a variety. The RR trait enables a unique weed control program to be used in alfalfa.

ROUNDUP READY WEED CONTROL STRATEGIES

Importance of Weed Control in Alfalfa

Successful weed control has been a continual challenge for alfalfa producers. The high forage quality requirements of the dairy industry in many areas necessitate nearly perfect weed control. In some regions, growers simply tolerate weed problems due to their inability to effectively control them. Similarly, it is important for the horse industry to have alfalfa hay that is free of noxious, low-quality, and poisonous weeds. This can be difficult with conventional herbicides. Typically no single herbicide controls all the weeds present in many alfalfa fields.

Weed management in alfalfa involves two distinct phases: weed control in seedling alfalfa during crop establishment and weed control in established stands. Weed infestation during crop establishment increases weed seed reserves and reduces seedling vigor and alfalfa stand, which can affect crop production for many years in this perennial crop. However, if protected from initial weed competition, a vigorous alfalfa stand competes well with later-invading weeds. After the crop is established, alfalfa stands naturally thin over years, making the crop increasingly susceptible to weed invasion. Weeds may reduce alfalfa yield, but

more importantly, weeds reduce the forage quality of alfalfa. Most weeds are lower in forage quality or palatability than alfalfa. Therefore weeds can significantly reduce the feeding value of hay for milk production and affect animal growth and health. Weeds such as lambsquarters (*Chenopodium* spp.) and pigweed (*Amaranthus* spp.) can accumulate toxic nitrate concentrations. Others such as common groundsel (*Senecio volgaris*) and fiddleneck (*Amsinckia* spp.) are poisonous to livestock and have been known to harm or even kill animals that feed on them.

Stand Establishment Trials

In 2002 to 2004, field trials were established in the intermountain area (spring- and fall- seeded), Sacramento Valley, and two locations in the San Joaquin Valley of California to compare the RR weed management system with standard weed control strategies under the diverse environmental conditions and weed spectrums encountered in California. Different Roundup rates, 1 (1.12 kg/ha) and 2 pounds (2.24 kg/ha) active ingredient (a.i.) per acre, and application timings were evaluated and compared with conventional standards. Three different herbicide application timings were evaluated based on the alfalfa leaf stage: unifoliolate to first trifoliolate, 3 to 4 trifoliolate, and 6 to 9 trifoliolate. The conventional standards used varied slightly depending on the location and the weed spectrum but included Raptor (imazamox), a tank mix of Pursuit (imazethapyr) and Buctril (bromoxynil) or Prism (clethodim), and a tank mix of Roundup and Pursuit. Sequential treatments (when deemed necessary) were evaluated to ascertain

the need for multiple treatments to control weeds that emerged after the initial application.

Crop Injury and Seedling Mortality

The Roundup treatments usually caused no injury. In cases where slight injury was observed, symptoms were short-lived and not evident at the time of first cutting. Raptor and Pursuit plus Buctril tank-mix treatments resulted in higher injury ratings, usually less than 20 percent at most locations. (Seedling mortality is not the same as early crop injury in RR alfalfa.) We observed a small percentage of seedling mortality in our RR alfalfa plots after the initial Roundup application. This is normal. Due to the polyploid genetics of the crop (similar population effects are observed for other traits in alfalfa), a small percentage of alfalfa seedlings do not contain the gene for Roundup resistance. Plant breeders from Forage Genetics International have indicated that seedling mortality of RR alfalfa varieties from commercial seed will likely be between 3 and 7 percent. This is not a problem with alfalfa, since usually more than 40 percent of seed sown fail to establish before the first or second cutting in a normal process of self thinning during stand establishment. However, if RR lines are not sprayed with Roundup during the seedling phase, these nonresistant plants may have a greater impact on the stand if sprayed at a time when the overall population is much lower (for example, after 6 months or a year after seeding). Therefore, it will be important to spray RR varieties at the 3 to 4 trifoliolate stage. Since one of the major incentives to plant RR alfalfa is to control weeds during establishment, this requirement should not be problematic for growers.

Herbicide Efficacy during Stand Establishment

Roundup applied at the proper alfalfa growth stage provided better than 95 percent control of nearly all weeds at all sites. Successful control of volunteer oats and wild radish in alfalfa using RR alfalfa and Roundup is shown in figure 1. Weeds controlled in the California experiments included:

- annual bluegrass (*Poa annua*)
- chickweed (*Stellaria media*)
- common groundsel (*Senecio vulgaris*)
- kochia (*Kochia scoparia*)
- nightshade (*Solanum* spp.)
- prickly lettuce (*Lactuca serriola*, see fig. 2)
- purslane (*Portulaca oleracea*)
- shepherd's purse (*Capsella bursa-pastoris*)
- swinecress (*Coronopus squamatus*)
- volunteer oats (*Avena fatua*)
- volunteer wheat (*Triticum aestivum*)
- wild radish (*Raphanus raphanistrum*)

Roundup was less effective than other herbicides on henbit (*Lamium amplexicaule*). While the 2.0 pounds active ingredient per acre rate (2.24 kg/ha) of Roundup resulted in more rapid weed kill, it was generally not needed for most weeds. The broad-spectrum efficacy of Roundup is well known by weed scientists, since it has been in use for decades. Roundup is one of the most-studied herbicides used in agriculture.

[Figure 1 omitted]

Timing of Application during Stand Establishment

The importance of application timing during alfalfa seedling development varied depending on weed species, location, and time of year. Generally, our trials showed that when Roundup was applied at the 3 to 4 trifoliolate stage, weeds were effectively controlled and

usually no second application was needed. Early applications allowed late germination of weeds, requiring a second application, while later applications (6 to 9 trifoliolate) allowed greater weed competition at early growth stages.

Roundup does not have soil residual activity, and weeds may emerge after application, especially if the alfalfa is small. At the intermountain site, a Roundup application made at the unifoliolate to first trifoliolate timing resulted in subsequent invasion of prickly lettuce (see fig. 2), and henbit, but shepherd's purse was completely controlled, as there was no subsequent emergence of this weed after the initial application. A second application in late winter was needed to control all the weeds. Similarly, a second application of Roundup was needed at one of the San Joaquin Valley sites (Five Points) when the first Roundup application occurred at the cotyledon to unifoliolate stage in alfalfa. Early Roundup timing resulted in excellent weed control in the other trials. In the San Joaquin County trial, where all Roundup timings performed well, a second flush of annual bluegrass and canarygrass (*Phalaris minor*) germinated in all treatments by early December. None of the conventional herbicide treatments controlled this second flush of weeds at this location, whereas a second application of Roundup was effective. The effectiveness of an early treatment appears to be a function of the weed species and its germination period and how soon after application the alfalfa canopy covers the soil surface.

[Figure 2 omitted]

Unlike standard herbicides, Roundup controlled weeds in the latest application period, 6 to 9 trifoliolate leaf stage. This indicates a greater flexibility with

Roundup compared with other options. However, weed competition was typically greater when weeds are allowed to compete with alfalfa as late as the 6 to 9 trifoliolate stage.

The RR system of weed management resulted in the best overall weed control of the treatments evaluated, and there was considerable flexibility in treatment timing. These results indicated that application of Roundup during the 3 to 4 trifoliolate stage is likely to result in the best control of emerged weeds. Extremely early applications, at the unifoliolate to first trifoliolate growth stage, are generally not advised because under some conditions subsequent weed invasion can occur since open areas in the young stand facilitate weed encroachment. The necessity of a second application depended on location, weed spectrum, and timing of the first application.

Efficacy in Established Stands

Field trials to study winter weed control in established alfalfa were also conducted at the same locations. In established stands, Roundup was compared with a commercial standard herbicide treatment for established alfalfa, Velpar (hexazinone) and paraquat. These are commonly used during the dormant period to control the winter complex of weeds that germinate during the rainy period in California. Roundup and the commercial standards were equally effective at most sites, providing excellent weed control. The commercial standards caused visible injury at some locations on both conventional and RR alfalfa. No injury was observed on RR plants from Roundup treatments. Roundup controlled the weeds at all sites except the San Joaquin County site, where burning nettle (*Urtica urens*), was not controlled (fig. 3). This

weed is not on the Roundup label. Tank mixes of Velpar with Roundup or paraquat controlled all weeds, including burning nettle. Our research showed that for difficult-to-control weeds, such as dodder (*Cuscuta* spp.) or small cheeseweed (*Malva neglecta*), applications should be initiated earlier than with other weeds, followed by a second application 2 weeks later. Several herbicides offer an alternative weed control strategy for herbicide rotations or tank mixes with Roundup if there are difficult-to-control weeds in the population.

[Figure 3 omitted]

Removal of Roundup Ready Alfalfa Fields

Eventually, an alfalfa stand must be removed when production falls to a level where the field is not as profitable or returns would be greater with a different crop. Roundup has been the primary herbicide used to remove depleted alfalfa stands; however, it obviously could not be used for this purpose in a field of RR alfalfa. The unwanted persistence of RR alfalfa in subsequent crops could potentially be a limitation of the technology if RR residual stands cannot be removed. However, alternative methods appear to be available to remove old RR alfalfa stands, but these methods must be adapted to specific crop-rotation situations.

Alfalfa fields are primarily removed by mechanical means such as cultivation with a plow or heavy disk or by undercutting the plants with a blade or rototiller. However, herbicides are sometimes used instead, alone or in combination with cultivation. Trials were conducted at several locations throughout California to evaluate the effectiveness of alternative herbicides for alfalfa stand removal. Numerous herbicides and

herbicide combinations were tested including 2,4-D, Banvel (dicamba), Stinger (clopyralid), Garlon (tryclopyr), Liberty (glufosinate), Aim (carfentrazone), and Harmony (thifensulfuron methyl). Treatments containing 2,4-D and dicamba tended to be the most effective, generally controlling greater than 90 percent of the alfalfa with the least crop rotation restrictions (see labels for restrictions). Alfalfa control improved to nearly 100 percent with all herbicides evaluated when followed by cultivation. These results demonstrated that chemical and nonchemical alternatives to Roundup exist for alfalfa stand removal in RR fields (fig. 4).

[Figure 4 omitted]

SEED PRODUCTION OF ROUNDUP READY VARIETIES

Alfalfa seed is grown primarily in the western United States on less than 100,000 acres (40,500 ha). Alfalfa is a cross-pollinated crop that requires bees to "trip" flowers to release pollen for seed production. In the United States, alfalfa seed production fields are pollinated with leafcutter bees (*Megachile rotundata* F.) in the Pacific Northwest and honey bees (*Apis mellifera*) in California. Some growers in Washington use alkali bees (*Nomia melanderi C.*) for pollination. Although viable seed production requires the transfer of pollen from one plant to another, control of pollen movement from seed field to seed field is important for maintaining genetic purity in alfalfa seed production, whether it is RR or not. Isolation standards are in place to maintain the purity of seed from varieties in adjacent seed fields. However, seed companies and alfalfa seed producers will need to establish new or modified protocols for production of RR seed, since the

seed may require higher standard of purity to address specific markets.

Gene Flow and Seed Purity

Understanding alfalfa outcrossing rate, gene flow, and pollinator behavior is very important to proper management of commercial alfalfa seed production. Current isolation standards for alfalfa in the United States are 165 feet (50 m) isolation from other alfalfa for certified seed and 900 feet (274 m) for foundation seed production. These are based on data collected in the 1980s, which used pest resistance genes as pollen flow markers between seed production fields (Brown et al. 1986). Recent studies used naturally occurring alfalfa marker genes to measure the potential for gene flow from source blocks to alfalfa plants at various distances from the source (St. Amand et al. 2000). This experiment was useful in studying the potential for transgene escape to feral alfalfa. A larger (1- to 2-acre [0.4- to 0.8-ha] source plot) 3-year study was carried out by Forage Genetics International using leafcutter bees. Both studies indicated that although gene flow can be detected over 1,500 feet (457 m) from the pollen source, it is reduced to less than 0.5 percent at 900 feet (274 m) and less than 0.2 percent at distances greater than 1,500 feet (see fig. 5; Fitzpatrick et al. 2003).

[Figure 5 omitted]

Preliminary studies conducted by University of California scientists in 2003 using honey bees as pollinators evaluated movement of the RR gene into herbicide-susceptible trap crops west and east of a 6-acre (2.4-ha) RR source plot at distances up to 2.5 miles (4 km). A significant decrease in gene flow with increasing distance from the source plot was observed (fig. 6). At 900 feet (274 m), pollen-mediated gene flow

was less than 1.5 percent, and it decreased to less than 0.2 percent near 5,000 feet (1.5 km). Gene flow continued to decline to a distance of 2.5 miles (4 km), where it was detected at a very low frequency (< 0.03%). Gene flow to the west and the east was not significantly different. It is clear that pollen-mediated gene flow decreases exponentially with distance, and the safe distance to minimize pollen flow is affected by type of pollinator.

[Figure 6 omitted]

Monitoring, Identification, and Quality Control

The preliminary data from honey-bee-pollinated field studies will be combined with data from future studies to develop strategies to preserve seed trait quality during seed production. Crop isolation practices are being developed by seed companies and producers to ensure seed purity and a minimum adventitious presence (unintended presence of genetic traits) in conventional alfalfa seed and hay. Although currently there are no standards in the United States to separate government-approved biotechnology traits, 1 percent adventitious presence has been suggested as the standard for adventitious presence of biotechnology-derived traits in non-transgenic varieties of seed crops in export markets. Handling of RR alfalfa seed may also require additional checks in place to prevent co-mixing of transgenic and conventional seed, depending on the market destination of the seed. For a review of crop identity preservation, see Sundstrom et al. 2002.

Variety Adaptation and Selection

Hundreds of alfalfa varieties have been developed for use in North America using conventional breeding methods of crossing and selection. These varieties are

adapted to the major alfalfa production zones and contain important genes for high yield, resistance to diseases, insects, and nematodes. Growers have been the beneficiary of decades of plant breeding by public institutions and private companies and competition between seed companies for their business. Several alfalfa seed companies will likely be marketing RR alfalfa varieties to satisfy a range of market conditions. Although Forage Genetics International has developed the initial RR alfalfa cultivars, other alfalfa breeding companies will have access to the trait. Fall dormancy (the genetic trait of fall and winter growth) is a major criterion for variety selection. In the first few years of release of the RR technology, the selection of varieties is likely to be limited to varieties within a small range of fall dormancies, with other fall dormancy classes to follow in subsequent years.

With the introduction of the RR trait, variety selection will include consideration of yet more "value-added" traits that should be considered in addition to yield and other traits. Generally, the protocol for selection of RR lines does not differ significantly from the selection of conventional lines. Fall dormancy group, yield potential, disease and insect resistance, and forage quality should all be considered, in addition to the value of the herbicide resistance. Calculations of potential benefits from the weed control technology should be compared to the added cost of the seed, relative costs of herbicide strategies, and potential limitations of the technology.

Seeding Rates

Recommendations for seeding rates vary significantly across the United States. California currently recommends a range of 15 to 25 pounds per acre (17 to

28 kg/ha) of seed, depending on seeding method and soil preparation. Although the price of seed is typically less than 2 percent of the total cost of production for growers, as the value and cost of seed increases, the relative economic impact of seeding rates and method increases. Precise seeding methods combined with proper soil preparation allow good control of seeding depth, seed placement, and soil-seed contact. Irrigation and early weed control during stand establishment reduce the probability of stand failure. These practices may enable growers to lower seeding rates, and thus manage cost of seed for higher-value genetics.

POTENTIAL BENEFITS OF ROUNDUP READY ALFALFA

Enhancing Weed Control Options

Current technology controls most but not all weeds. Certain weeds, such as Canada thistle (*Cirsium arvense*), dandelion (*Taraxacum officinale*), dodder, nutsedge, (*Cyperus* spp.) bermudagrass, (*Cynodon ductylon*), and quackgrass (*Elytrigia repens* L.) are particularly problematic. Annual weeds such as barnyardgrass (*Echinochloa crusgalli*), pigweed, lambs-quarters, foxtails (*Setaria* spp.), nightshades, downy brome (*Bromus tectorum* L.), and mustards (*Brassica* spp.) can be troublesome at certain times. A subset of these weeds can be controlled by a combination of currently available herbicides in tank mixes or multiple applications, but Roundup controls a broader weed spectrum and may be more efficacious than most currently available herbicides or herbicide combinations (see the section "Roundup Ready Weed Control Strategies," above).

Weed Control Flexibility

While many available weed control options have fairly well-defined requirements and restrictions as to application timing, temperatures, and environmental influences, Roundup strategies are likely to provide a more-flexible option to growers. Although timing with Roundup applications is to some degree still important, it may not prove as important as it is with some of the alternative methods. The high degree of flexibility and broad-spectrum weed control are the principal benefits of RR alfalfa.

Potential Economic Benefits

Roundup Ready technology has the potential to provide more-reliable stand establishment and improve alfalfa yields and forage quality due to reduced weed contaminants. The value of alfalfa per ton may be improved, since pure alfalfa is usually worth 20 to 50 percent more than weedy hay. Other possible benefits include extended life of stands and improved crop safety compared to other weed control options. However, as of this writing, the economic benefits of the RR technology are not entirely clear, since the pricing structure has not yet been determined.

Animal Feed Safety and Animal Health

Contamination with poisonous, antinutritional, or simply unpalatable weed species is a common hazard of livestock feeding. Veterinary diagnostic labs and veterinarians each year report many cases of horses, cows, and sheep that are killed or sickened after consuming alfalfa that has been contaminated with such weeds. Some weeds simply lower animal performance or milk production, but others can kill. Roundup Ready alfalfa provides a simple option to minimize the risk of consumption of poisonous or

unpalatable weeds by livestock, and it has the potential to improve animal welfare and production by increasing the feeding of pure, weed-free, high-quality alfalfa hay.

Water Quality

In addition to the benefits in terms of crop productivity, crop quality, animal production, and value, RR technology may replace some herbicides that have the potential to contaminate water supplies. Several herbicides used in alfalfa during the winter (dormant) period have been detected in wells in California's San Joaquin Valley (Troiano et al. 2001). To the extent that it replaces those options, RR technology could lessen this environmental concern, since there is little evidence of off-site environmental impacts from glyphosate (Thompson et al. 2004).

Preventing Spread of Noxious Weeds

Although all successful weed control strategies share this characteristic, RR alfalfa could improve the ability of growers to slow or stop the spread of noxious weeds in hay. The U.S. Forest Service and other agencies have encouraged the use of certified weed-free hay to be brought into natural areas for livestock and pack horses to prevent the spread of noxious weeds into environmentally sensitive areas. Roundup Ready technology could aid in that effort by creating "weed-free" alfalfa hay.

POTENTIAL PROBLEMS WITH ROUNDUP READY ALFALFA

Weed Control Limitations

Although the spectrum of weeds controlled by Roundup is impressive, certain weeds are not completely controlled by Roundup. These include cheeseweed (*Malva parviflora*), burning nettle (*Urtica*

urens), filaree (*Erodium* spp.), and others. In addition, Roundup has no residual activity that controls weeds for longer periods, as some conventional herbicides do. Roundup Ready technology should not be viewed as a panacea, but as a component of an overall weed control effort on a farm. Weed control strategies that incorporate cultural methods and rotation of herbicides will be needed to combat weeds not completely controlled by Roundup in order to prevent weed shifts.

* * *

Gene Flow to the Environment

As the RR gene is new to alfalfa, its effect on the environment must be studied in the context of gene movement and persistence in plants. Genes (DNA) introduced through biotechnology are passed on from generation to generation and to and from close relatives as any other gene in plants. Genes can be transferred among varieties or closely related species by gene flow or seed mixtures. It is important to establish strict management protocols to ensure varietal purity and minimize gene flow to and from unwanted sources, also known as adventitious presence. Gene flow is affected by sexual compatibility, flower characteristics, pollen viability and quantity, proximity of neighboring plants, pollinator activity, and environmental conditions. In the United States, there are no sexually compatible wild relatives to alfalfa; feral alfalfa is the only plant it can successfully cross with.

The potential environmental impact of the gene flow from RR alfalfa to feral alfalfa must be understood in terms of "fitness." Alfalfa generally is not considered by weed scientists to be an invasive weed, but it does occur along roadside ditches (often sown by

state and local highway managers) and in agricultural areas. If the RR gene is transferred to feral alfalfa, it is not clear that these plants would have any natural advantage over conventional alfalfa, or any greater weedy characteristics, except where Roundup is sprayed. Research is currently being conducted by University of California scientists to determine the proper weed management programs to prevent outcrossing and to control feral alfalfa. As our alfalfa removal studies have shown, several commercial herbicides are currently available for removal of RR alfalfa.

For the 22 million acres (8.9 million ha) of alfalfa in the United States, the issue of crossing RR alfalfa with feral relatives may not be a major issue, since these fields are typically harvested in the prebud to midflower stage of development, thus little pollen flows and few viable seeds are set (typically none). The issue of gene flow is primarily a concern in seed production, where pollen flow is necessary for seed set. Currently, less than 0.5 percent of the alfalfa grown in the United States is grown for seed.

Market Acceptance of Roundup Ready Hay

Roundup Ready alfalfa will be the first genetically enhanced alfalfa product to be marketed commercially. It is anticipated that the first commercial crops will be grown in 2005. In most parts of North America, the majority of alfalfa is fed on-farm, but in the western United States, the majority of hay is offered for sale to dairy, with the remainder to horse, beef, and export customers. Nationwide, most alfalfa is consumed by the U.S. dairy industry, where it is considered the premier forage crop. For example, in California, dairy cows consume greater than 75 percent of the state's

alfalfa crop. Thus, consumer acceptance of RR hay is highly dependent upon the acceptance of the dairy industry, which in the last decade has absorbed four to six new technologies related to genetically modified crops. Because of this, most experts believe that the dairy industry will, by and large, accept RR alfalfa. The horse industry may provide initial resistance, since individual preferences come to the forefront, but some buyers may be attracted to the "weed free" aspect of RR alfalfa. The organic market for hay is small and will likely reject RR alfalfa, as it does other biotech crops. Except for some specific markets such as organic, most alfalfa experts do not foresee significant market resistance to RR hay, with the exception of the export market.

Exports

The United States exports about 4 percent of its alfalfa to Japan, Korea, Taiwan, Mexico, and Canada. About 80 percent of U.S. alfalfa hay exports are destined for Japan (see http://www.fas.usda.gov/ustrade), with approximately one-quarter shipped through California and three-quarters shipped through Oregon and Washington ports (see http://aams.usda.gov/lsmnpubs/PDF_Monthly/CALHAY2003.pdf). The majority of exported alfalfa is grown in the western states. Exporters in these states have expressed concern that their overseas customers may not accept the presence of a genetically modified crop. Export consumer preference may also be highly dependent on price. At a minimum, buyers will need to initially differentiate transgenic hay from nontransgenic hay in their export lots. It is likely that the tools and management practices to achieve this will be in place prior to commercialization. For example, sensitive tests to

detect the presence of the RR gene in hay and seed are currently being developed.

Full approval by government agencies for animal feed and food in the United States and major export markets is currently being sought. The protein responsible for Roundup (glyphosate) tolerance has already been approved for feed and food use in other crops in the primary export countries. Roundup Ready alfalfa will not be commercialized until regulatory and safety approval is obtained in the United States and Japan, according to Forage Genetics International and Monsanto. The Japan Feed Trade Association stated in July 2002 that it had no concerns about RR alfalfa, since biotechnology-enhanced canola, soybeans, corn, and cottonseed have been used successfully for feed in that country.

FOOD SAFETY

The RR alfalfa system is currently being evaluated for safety in food, in feed, and in the environment. The safety of biotechnology-derived crops in food and feed is measured using the principle of substantial equivalence (FAO/WHO 1996). The idea is to compare feed and food from a biotech crop to its nearest nonbiotech counterpart that has a long history of being safe to consume. In this context, the effect of introduction of the new protein in feed or foods is studied for its toxicity, allergenicity, and any modifications in nutritional value in whole foods and feeds. The gene introduced in RR alfalfa is the same gene used to create other RR crops such as corn, soybeans, oilseed rape, and cotton. As a result, the impact of the introduction of this gene on ecological, environmental, and food and feed safety has been

studied extensively for over 8 years since its initial large-scale introduction into soybeans in 1996 in the United States. These studies have shown that RR crops are substantially equivalent to conventional crops for their use as foods and feed (Hammond et al. 1996; Taylor et al. 2001). Dairy and beef cattle, swine, and poultry producers can currently feed alfalfa or other crops treated with Roundup. The United States Department of Agriculture, Environmental Protection Agency, and Food and Drug Administration regulate ecological, environmental, and food and feed aspects of biotechnology traits in the United States, respectively. Animal feeding studies are currently being conducted to evaluate any effects on growth, quality, and safety of RR alfalfa to livestock production. Roundup Ready alfalfa will not be commercialized until the EPA and FDA have concluded that it is substantially equivalent to conventional alfalfa based on safety data and residue studies (see Van Deynze et al. in press for review).

SUMMARY

Roundup Ready alfalfa is likely to be commercialized in 2005, contingent upon regulatory approval and logistical considerations. This technology combines the insertion of a gene conferring resistance to glyphosate in alfalfa varieties, enabling applications of the broad-spectrum herbicide Roundup or its equivalent. It is likely to expand weed control options available for alfalfa growers, potentially enhancing yield, forage quality, and profitability. Economic benefits will depend on pricing structures defined by the industry. There are potential environmental benefits if current herbicides present water quality or worker-safety

concerns, The major concerns associated with RR technology are the potential for weed shifts, weed resistance, potential gene flow during seed production to feral alfalfa, stand removal, and market acceptance for exports. Management strategies to address these concerns have been suggested. Roundup Ready alfalfa is being extensively studied by public and private researchers to develop management protocols and address environmental questions for this technology. This technology provides an additional weed management tool for growers, the principal feature being its simplicity, flexibility, and broad-spectrum weed control.

[Exhibit C]

MARKET SENSITIVITY AND METHODS TO ENSURE TOLERANCE OF BIOTECH AND NON-BIOTECH ALFALFA PRODUCTION SYSTEMS

Dan Putnam[1]

ABSTRACT

Roundup-Ready® alfalfa was released in June of 2005, the first trait to be commercialized in alfalfa (*Medicago sativa* L.) using biotechnology. Traditional alfalfa varieties will likely be grown in close proximity to these new biotech varieties. While most users will probably not be sensitive to the presence of these varieties, other markets (particularly export and organic) will request hay that is free of the biotech traits. The acreage estimated to be sensitive to this trait is estimated to be less than 3-5% in the US, but some regions, markets, and growers will be more sensitive than others. Methods to assure identity and preservation of non-biotech alfalfa include understanding the potential for gene flow, reducing feral alfalfa, and improved methods to maintain commercial identity, including the use of test strips which confirm the absence or presence of RR hay. The potential for gene flow from alfalfa hay field to hay field differs significantly from gene flow in seed production

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due to a series of 'environmental filters' under forage production which are likely to prevent significant gene movement. Successful coexistence of biotech and non-biotech alfalfa hay for sensitive markets should be feasible with a higher degree of awareness of these issues and several simple management steps.

Key Words; biotechnology, varieties, organic farming, exports, organic hay, weed control, roundup-ready, economics, markets

INTRODUCTION

During the past decade, biotech-origin traits have been successfully commercialized in corn, cotton, and soybean, particularly the Roundup-Ready™ (RR)[2] trait. On June 14th, 2005, the RR trait was de-regulated in alfalfa (USDA, 2005), allowing biotech alfalfa varieties to be sold which are tolerant to the herbicide glyphosate (Roundup®). This act enabled not only the commercialization of the first biotech varieties in alfalfa, but also provided a new previously-unavailable weed management system for this crop. The first commercial fields were planted in 2005, with the first major biotech forage products to be utilized in 2006.

Alfalfa (*Medicago sativa*) in recent years has overtaken wheat as the third most important crop economically in the United States, exceeded only by corn and soybean (USDA-NASS, 2004). Over 22 million acres are harvested each year, with the largest alfalfa producing states being in the West and upper Midwest, particularly CA, ID, IA, NE, MN, SD and WI. Alfalfa

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[2] Mention of a product does not imply endorsement of that product nor disparagement of similar products which may serve the same function.

is primarily used for dairy production, but is incorporated into beef, sheep, and horse grazing and hay systems as well.

If adopted by growers, the RR technology may cause profound changes in the way that alfalfa growers approach weed control as well as the varieties that they grow (Doll, 2003; Orloff et al., 2003; Van Dynze et al., 2004). Although research on the issues surrounding this technology is on-going, the weed control efficacy of Roundup is well known, and several comparative studies have been published (Van Dynze et al., 2004).

However, the release of the first commercial biotech trait in alfalfa also presents several challenges. From a grower's perspective, the questions with this technology are related to crop management, economics, weed management, stewardship of the trait, environmental issues, and utilization or marketing of the hay. Since biotech and non- biotech alfalfa varieties will likely be grown in close proximity, growers of both types will need to understand the issues associated with stewardship of the trait and the potential impacts of these coexisting systems on markets, crop profitability, and risk. This paper provides an overview of these issues, and suggests steps to assure stewardship of both biotech and non-biotech alfalfa varieties in hay production and marketing systems.

UNDERSTANDING SENSITIVITIES OF ALFALFA MARKETS AND CONSUMERS

Biotech traits have been used in animal feeding systems for more than a decade now. Over 100 digestion and feeding studies examining the effects of feeding GE crops to various food-producing animal species (e.g., beef cattle, swine, sheep, fish, dairy cows, water buffalo, and chickens) have shown that DNA or

proteins from biotech crops are not detected in milk, meat, eggs, or other products from animals that consume these crops (Cullor and Rossitto, 2004, Van Dynze et al., 2004, Van Eenennaam, 2005). The National Academy of Sciences has concluded that biotechnology is no more likely to produce unintended consequences for human food risk than conventional methods, and actually may hold some advantages, since the genetic changes are more defined than conventional crossing (NAS, 2004). The USDA uses the standard of 'substantial equivalence' in judging the safety in utilization of biotech crops, and has determined that Roundup Ready alfalfa is safe to enter the US feed market (USDA, 2005).

Nevertheless, some markets may be sensitive to the presence of biotech alfalfa, and will wish to maintain crops which are considered 'free' of biotech traits. Thus understanding the utilization patterns of alfalfa and the markets or uses for alfalfa which might be sensitive to the purchase or use of RR alfalfa products is important to the issue of coexistence of biotech and non-biotech systems.

How is alfalfa used?

While it is difficult to know with a large degree of certainty the utilization and disappearance of alfalfa in the United States, there are three major consuming markets for alfalfa hay. These are: alfalfa for dairies, alfalfa for beef, and alfalfa for horses. More minor, but still important uses for alfalfa forage include alfalfa hay for export, alfalfa for small ruminants (sheep, goats), alfalfa meal for processed feeds, and alfalfa pellets for pets and rabbits. Alfalfa sprouts for human consumption is a by-product of the seed industry, and

not related to forage production, the major use of alfalfa.

This discussion is limited to the markets for alfalfa hay, not seed, which presents separate and important issues with regards to biotech traits (Mueller, 2004). Alfalfa seed is a more localized issue, with a scope of less than 200,000 acres in several western states, whereas alfalfa forage impacts over 22 million acres of cropland in the US. Of these uses for alfalfa forage, dairy is clearly the most important, and must be considered the 'driving force' for alfalfa production in the United States.

Alfalfa for use on dairies.

The use of alfalfa for dairy production is by far the largest consumer of alfalfa in the nation. In California, we estimate this amount to be about 75% of the production, and it could be higher, although no agency keeps close statistics on utilization of hay or forage. The other major forage for dairies is corn silage, but alfalfa is often considered the 'staple' of dairy production in the US.

Utilization of alfalfa for dairies can be divided into on-farm use raised by dairies and fed on-farm, vs. hay raised independently and sold to dairies; these systems have clear differences in terms of marketability and acceptance. On-farm feeding is more common in Eastern and Midwestern US states, whereas alfalfa hay is mostly sold as a cash crop in western states. For on-farm use, marketing issues are confined largely to the views of the dairy or producer, as well as to the marketing of milk and meat. For cash hay producers, the market signals are purely through price and willingness to buy. For a cash hay producer, the worst fate is being stuck with hay that simply will not sell—a

common occurrence for hay discounted for quality traits, not considering biotech traits.

It is anticipated that the dairy industry will not, with some notable exceptions, be highly sensitive to the presence of a biotech trait in alfalfa. This is due to the fact that the dairy industry has already absorbed at least 6-8 GMO traits which are currently components of the milk or milk-product production system. *Bovin Somatotropin* (BST), a naturally-occurring hormone produced via biotech methods, has been used for over a decade on many dairies. This was followed by the introduction of genetically engineered crops (both Roundup-Resistant and crops with the *Bacillus thurengensis* (Bt) gene), particularly corn, soybean, canola meal and cottonseed, all of which feature prominently in dairy feed rations. Additionally, most cheese is now produced with biotech-based rennet, produced in fermentation vats since 1990 rather than by sacrificing calves for rennet. While some have raised concerns about the inclusion of these biotech traits in our milk supply, the predominance of these biotech traits in the dairy system has by-and-large not proved to be a major marketing issue.

The exception to this is organic dairy producers. Organic dairies have rejected biotech crops as a component of certification for organic status (USDA). Organic milk is a small but growing component of US milk production. The number of certified organic milk cows reportedly increased by 277% from 1997 to 2001, but still constitute less than 1% of the total US milk production (Miller, 2005).

Organic dairy producers will demand hay which originates not only from biotech-free alfalfa crops, but from fields that have been approved for organic

production according to the certification standards to which they subscribe. Since organic alfalfa precludes pesticides, the RR trait would be useless anyway, since Roundup is also precluded. Therefore, organic dairy producers will demand alfalfa from certified fields that do not contain biotech varieties.

Thus, although specific dairies will demand biotech-free alfalfa, at this point in time, the vast majority (e.g. 95 to 99%) of dairies in the United States are not likely to be highly sensitive to the inclusion of a biotech trait (RR alfalfa) in rations.

Alfalfa for Beef-Sheep-Goats.

The quantity of alfalfa disappearance into the nation's beef industry is also not known, but a larger percentage of non-alfalfa forage (grass hay, grazed forages and corn silage) is fed to beef cattle than to dairy cattle. Of these consumers, less than 1% of beef production is organic (NCBA, 2005), but the National Organic Trade Association projects growth to be 30% per year through 2008.

However, for the same reasons cited in the above paragraphs, it is highly unlikely that the vast majority of beef producers will be sensitive to the use of biotech alfalfa in rations. The beef industry, similar to dairy, has already absorbed a number of GE-based traits in the feed ration, the most prominently biotech corn and soybean. The food safety concerns of the public with beef are generally more focused on specific disease issues (e.g. bovine spongiform encephalopathy or Mad Cow), or with the use of antibiotics, steroids or growth hormones in beef production, rather than whether the feed was produced using genetically modified crops.

However, the categories of organic beef and 'natural' beef will likely entail a demand for hay which is free of

biotech traits. Grass-fed beef is another specialty category for discerning consumers, but the presence of biotech alfalfa will not be important to this market for obvious reasons, While organic beef requires the use of non-biotech feeds, conventional beef producers are not likely to be highly sensitive to the presence of biotech alfalfa.

Sheep and goat enterprises are tied to ethnic or specialty uses, and thus may be somewhat more sensitive than beef to the use of Biotech alfalfa, but the quantity of utilization by this class of livestock in the United States is very small.

Alfalfa for the Horse Market.

Alfalfa and alfalfa-grass mixtures are the most important hay crop for the US horse industry (Shewmaker et al., 2005), and weed-free bright green alfalfa or grass-alfalfa mixes are highly sought by horse owners. There are probably 6-7 million horses in the US, the biggest states being Texas and California. Rodiek (2004) estimated that there were of 650,000 horses in California. Horses are probably a significant consumer of the nation's alfalfa crop, but again, exact data on the disappearance of alfalfa into this market does not exist. It may be on the order of 5-15% in California. If each horse in California consumed 5 lbs of alfalfa/day (a flake or two) this would consume about 8% of our production each year (Rodiek, 2004), but I should emphasize that the exact dimensions of this market are not known.

Horse owners do not really consist of an 'industry' in the same way as dairy and beef producers, but is made up of thousands of individual buyers, each with their own concepts of animal nutrition. The use of professional nutritionists is rare, so scientific

approaches to feeding of horses are not common. Horse owners are largely urban, not farmers in the traditional sense. Additionally, most horses are largely pets rather than income-producing enterprises. Thus, individual prejudices are much more likely to enter into hay buying decisions for the horse markets than for dairy or beef (Rodiek, 2004; Lawrence, 1998). We should also keep in mind that alfalfa isn't the only hay of choice—timothy and grass hays are also desired by this market segment.

The horse market is widely known amongst growers for its individualistic and idiosyncratic approach to purchasing hay. While some buyers prefer pure alfalfa, others insist upon grass-alfalfa mixes or pure grass hay. Color is a major factor, complaints are frequent, and this market is full of stories of diverse buyers, each of whom has their own concepts of the 'best' hay. Many horse owners are not aware of the methods used to produce hay, and may not be aware of the presence of biotech alfalfa. Due to the strong subjectivity of the horse market, it is clear that some individual horse owners will resist the feeding of RR alfalfa due to their own preferences and opinions about biotech, but this is not likely to be universal.

The converse may also be the case, since each year a sizeable number of horses are sickened or die due to the presence of poisonous weeds in hay (Pushner, 2004), which could be alleviated by RR alfalfa. There have as yet been no documented side-effects due to the consumption of biotech feeds, though biotech feeds have been consumed in large quantities for at least 5 years. This fact may favor pure, weed-free RR alfalfa compared with weedy hay for some horse owners who buy alfalfa hay. However, since the range of

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viewpoints on the feeding of horses is wide, there will undoubtedly be some horse owners who will reject biotech alfalfa.

Alfalfa for Exports.

Some alfalfa hay is exported to foreign countries, mostly from the western states of WA, CA, OR, ID, UT, and NV (western ports account for >99% of the exports from the US). In these states, exports may be about 4.5% of production (Table 1). On a national basis, exports account for about 1% of the production. However, in certain regions export percentage is much higher, such as in central Washington, and Imperial Valley of California. The percentage of alfalfa grown for export in these areas is much higher than nationally, or even within those states. There is some dispute about the numbers. Some experts estimate exports from Washington state to be as high as 34% of the state's production for alfalfa (T. Woodward, WSU Cooperative Extension, pers. Comm.), and in California perhaps 1.5% of the state's production (Seth Hoyt, CDFA, pers. Comm, 2005). Coarse hays, such as sudangrass, and grass-seed straw are more important in some areas for hay exports than alfalfa.

It should also be kept in mind that, though a haygrower may export only a portion of their hay (e.g. one or two cuttings), the market acceptance (or lack of acceptance) of the export market in these regions will impact the whole acreage, since hay for export is one component of a multi-use market strategy for that grower. For example, it is estimated that over 80% of the growers in the Columbia Basin of Washington will export at least one of their harvests each year. Therefore, the acreage which might be sensitive to biotech alfalfa due

to exports is larger than indicated by the production actually exported.

It is clear there will be resistance to biotech traits in alfalfa grown for export. The vast majority of exported hay goes to Japan (Woodward, 2004). Exporters have in some cases insisted on written contracts with producers stating that they will guarantee biotech-free alfalfa for the Japanese markets because most importers have asked for biotech-free alfalfa. Thus, initially, growers who wish to sell into the hay export market must be careful to keep hay for that market separate and distinct from biotech-based alfalfa varieties.

[Table 1 omitted]

Official approval of the Japanese government for importation of RR alfalfa is pending, and some believe should be completed by Spring, 2006. However, official approval only partly addresses the market sensitivity issue, since some importers are likely to continue to insist upon non-GE hay. The initial requirements for the commercialization of RR alfalfa in 2005 include restrictions that prohibit exportation of the hay by growers. Additionally, seed sales have been restricted in regions such as Imperial Valley and Central Washington where exports are important. The Washington State Haygrowers Association has requested a delay in the release of RR alfalfa in that state until Japanese buyers have indicated they would accept that hay (see website). Similar requests have been made in the Imperial Valley.

Are Hay Markets Rational?

Although an economist might argue that markets are truly rational reflections of supply and demand, there are numerous examples of irrationality entering into

marketing of hay in terms of quality preference. Consumer preference for factors which are not supported by scientific principles are common for the horse market, the export market, and to a lesser degree for the dairy market. If one accepts the business axiom 'the customer is always right', growers must respond to these factors or risk loosing their markets.

Alfalfa does not receive government subsidies, and follows free market conditions to a greater degree than most agricultural commodities. Market quality standards are highly unregulated. Although markets reward genuinely higher quality hay as judged by lab analysis (Putnam, 2004), there are numerous examples of highly subjective and non-scientific factors entering into the sales process for alfalfa hay. With horse buyers, fears about 'something in the hay' affecting health of animals, and prejudices about alfalfa hay commonly enter into negotiations or willingness to buy. With exporters, perception about 'quality' may be entirely contrary to known scientific principles of forage quality factors. A case in point is the demand for 'long seed heads' in timothy hay for export—such features are entirely contrary to known scientific attributes of forage quality (hay with few seed heads is likely to be higher in quality). In California and other locations, dairy buyers and hay sellers commonly argue over a few tenths of a point TDN, ADF, NDF or CP value, when it is abundantly clear that the process of forage testing cannot deliver this degree of precision (Putnam 2004). Some markets will commonly gravitate toward physical factors (such as bright green color) which are poor predictors of quality from an animal feeding perspective.

This reality of subjective factors (or 'irrational' factors) impacting markets is pertinent to the biotech question. The current concern about biotech traits in crops is linked in vague ways with a whole range of concerns about food safety, from Mad Cow Disease to hormones, to pesticide residues and nitrates, as well as the 'corporatization' of the food supply and environmental impacts, even though these are all distinct issues. This is the case in Japan, but also Europe and US where these concerns are often lumped together in the same discussion. Markets may be affected in the short run by these artificially linked factors, due to the desire simply to have only 'safe' food and feed. We should also not forget the natural inclination to reject certain products due to simple protectionism and price bargaining.

Summary of market sensitivities for alfalfa.

In summary, the majority of users of alfalfa are not likely to be sensitive to the presence of the Roundup Ready trait in alfalfa for either on-farm use or hay for market sale. A minority of the users of alfalfa (probably 3-5%) are likely to be sensitive to biotech alfalfa, specifically the organic sector (dairy and beef), a small portion of the horse market, and a majority of growers who participate in alfalfa hay exports.

However, it is also clear that it is important to protect these segments of the market that may be sensitive to a biotech trait. An organic grower and an export grower who wishes to maintain crops without GE traits has as much right to maintain their production methods and prevent loss of markets as do other growers who wish to try new GE traits on their farms. Thus, all growers need to be aware of the sensitivity of their specific markets to this trait, and discover

methods to allow coexistence of both biotech and non-biotech traits within their region without unduly upsetting market patterns.

IMPORTANCE OF ALFALFA FOR CROP ROTATIONS AND ORGANIC SYSTEMS

Some have raised objections to the release of RR alfalfa due to the potential for loosing its soil benefits for organic systems (Pridham, 2004). Alfalfa 'the queen of forage crops' is highly valued not only for its high yield and high quality as an animal feed, but for its N_2 fixation, soil benefits, crop rotation, and wildlife habitat (Russelle, 2004, Putnam, 2001). While Roundup Ready alfalfa varieties have not been fully tested for their N_2 fixation ability, there is no reason to suspect that these RR varieties will be any different than conventional varieties in this respect. Early results on their yield potential indicate similar yields to conventional varieties, and the plants are well-nodulated and similar in quality to conventional lines (Putnam et al., 2004). Roundup-Ready varieties should provide some of the same benefits to rotations as do conventional varieties, and growers will continue to have a choice to choose RR and conventional varieties for this purpose.

It is possible that the RR trait may open up other options for rotations, overseeding, and minimum tillage practices not previously available to growers, which could reduce fuel or nitrogen costs (Doll, 2003). Proponents of organic farming have objected to the release of RR alfalfa (Pridham, 2004) due to the potential for loosing its soil benefits for organic systems. However, biotech crops are prohibited in organic systems, and RR alfalfa would not be used in any event, since the only value of these varieties is to use a different herbicide—banned in organic systems in

any case. The objection to GMOs on the part of organic and export-based growers is primarily primarily based upon philosophical objections to biotechnology, or customer-based negative perceptions of the trait. The presence of a GE trait in alfalfa should have a neutral effect on the soil benefits of alfalfa, and, although it's too early to tell, may enhance some of these properties if new tillage practices or production systems are enabled. Some weed scientists have predicted that RR alfalfa stands may last longer since weeds can be effectively controlled, but that remains to be seen.

WILL THE INTRODUCTION OF RR ALFALFA INCREASE HERBICIDE USE OR WATER CONTAMINATION?

Most California growers currently use herbicides during stand establishment or for maintenance of weed-free stands. If RR alfalfa is adopted, it would likely represent the replacement of currently-used herbicides in most cases in fields planted with RR alfalfa. Therefore, it is not anticipated that the introduction of this GE crop would increase herbicide in total, but where adopted, will cause a shift of herbicide use to glyphosate. It should be emphasized that, even where growers are not concerned about their markets, they may not adapt the technology due to cost factors or weed management factors; it should not be considered a panacea (Van Dynze et al., 2004).

Where glyphosate (Roundup) replaces other herbicides that are more highly soluble and subject to runoff, the introduction of this technology may reduce the overall impact of herbicides on the environment. Several winter-applied hebicides currently used in California have been detected in wells in the Central Valley and are of strong concern to regulators (Prichard, 2002).

Growers who use these herbicides are subject to severe restrictions for use based upon soil type and groundwater characteristics. It is anticipated that glyphosate presents a lower risk to the environment compared with some of these herbicides (DPR website, State of California).

METHODOLOGIES FOR MAINTAINING MARKET IDENTITY

Alfalfa hay growers who wish to sell into markets sensitive to biotech traits (such as hay for export or organic production) may be concerned with methods to ensure co-existence of these genetically diverse systems of biotech-origin and non-biotech origin alfalfa varieties. The stewardship of purity of both non-biotech and biotech traits within a region will depend upon a range of practices, beginning with seed production and purity.

1) Select Certified Varieties for Seed Purity and Quality

The first step in stewardship of both biotech and biotech-free alfalfa is choice of pure seed. It is difficult to overemphasize the importance of variety and seed choice for those hay growers who are concerned with the purity of their alfalfa stands and/or who are selling into sensitive markets. This is likely to be the most crucial step in assuring trait purity in a hay product.

Alfalfa seed is produced on small acreage in western states of the Pacific Northwest, California, and a few other Western states. Seed production is an exacting enterprise, and seed growers take pride in their abilities to manage a complex system to produce high quality seed (Mueller, 1996). Industry standards for isolation have been developed, and Crop Inspection and Certification Services are available in each

seed-producing state to assure seed purity which includes variety identity, seed quality, and lack of contamination with weeds or foreign matter. The incorporation of biotech traits in alfalfa seed production has been considered in detail elsewhere (Mueller, 2004).

Choice of certified seed should be combined with as the assurances, reputation, and standards of the seed company. Thus the first step in the process of stewardship is selection of certified varieties backed by a company with high standards for seed production.

2) Understand the potential for Gene Flow

Adventitious Presence (AP) is the presence of an unwanted trait (such as a biotech trait) in a variety meant to be free of that trait. Alfalfa is a cross-pollinated crop that requires insect pollinators (usually honeybees or leafcutter bees) for seed production. Successful seed production requires the transfer of pollen from one plant to another. Thus, adequate isolation of alfalfa seed fields is required to assure that very little pollen transfers from one crop to another during seed production.

The potential for gene flow in alfalfa harvested for hay is not the same as the potential for gene flow in alfalfa seed crops due to difference in production methods. However, the **upper limits** for the possibility of gene flow in hay fields can be understood by examining what happens during seed production (Mueller, 2004, Ricker et al., 1988). Studies in seed fields in Idaho, using leafcutter bees as pollinators, showed gene flow (AP) from a RR alfalfa seed crop to a non-biotech crop to be about 1.5% at 500 feet, less than 0.5% at 900 feet (274 meters), and zero at 2,000 feet (610 meters) (Fitzpatrick et al., 2002). Honeybees generally have longer flights than leafcutter bees and a study in

California using honeybees as pollinators showed gene flow (AP) to be 1.5% at 500 feet, below 1% at 2500 feet (0.8 km), but sporadic gene flow (<0.03%) could be detected up to 2.5 miles away (Teuber et al., 2004; Van Dynze et al., 2004). These estimates are under conditions to maximize pollination and seed production, conditions which do not generally occur in alfalfa hay fields.

3) Understand the limits to alfalfa gene transfer from hay fields to neighboring hay fields

Will the Roundup-Ready gene (or any biotech trait) be transferred from alfalfa hay field to another hay field? The short answer is: very rarely, and only with great difficulty under most conditions. Although gene transfer from alfalfa to other alfalfa hay fields is theoretically possible, there are a range of environmental barriers to such transfer, which would make significant movement from a biotech alfalfa crop to a neighboring non- biotech alfalfa field very unlikely. Additionally, there are steps that growers can take to limit traits from moving from field to field.

The potential for a trait to be successfully transferred from one alfalfa hay field to another, sufficient to cause Adventitious Presence (AP) in hay is dependent upon a series of steps (Figure 1). These steps are significantly different for hay than for seed crops. Alfalfa seed fields are managed to maximize flower production, pollen transfer, and seed maturation and seed yield. However, alfalfa forage production fields are managed to maximize biomass production of high quality forage for animal production. Seed production in hay fields in most parts of California is minimal, although some flowering does occur. The vast majority of alfalfa fields

in the California are harvested with only a small amount of flowering and zero seed production.

In seed fields, for adventitious presence to be transferred from one field to another, pollen has to be transferred, resulting in seed that is harvested with the AP trait. However, for AP to occur in hay fields, this must occur, along with several additional steps—that seed must 1) remain in the field, 2) fall to the ground and germinate, and 3) that seedling must survive to become a component of the new hay crop.

Each of these steps (Figure 1) have a certain probability of occurring. While the exact probabilities of each of these steps are not known with great certitude, an analysis of the potential for unwanted AP in hay begins with an estimation of the probability of these steps occurring in practice.

a. **Probability of Flowering**. In order for gene transfer to occur, flowering must be simultaneous between two fields. Historically, it was recommended to harvest alfalfa at 10% bloom. However, many alfalfa fields harvested for dairy production are harvested in the bud or vegetative stages for high quality, when only occasional flowers are present. Nevertheless, we should assume that some flowering will be present at harvest of each hay crop, even if only a few flowers in a field. In most cases this will range from an occasional flower to 10% flowering, but under hot midsummer conditions, or with delayed harvests, the percentage of plants flowering tends to be higher. Flowering is particularly high during summer months, and under desert conditions, such as the Imperial

Valley, with a correspondingly higher risk for cross-pollination.

b. **Probability of Pollinators.** For pollen to flow between fields, pollinators must be present. These include honeybees (*Aphis mellifera* L.) Alkalai bees (*Nomia melanderi* Cockerell) and leafcutter bees (*Megachile rotundata* Frabricus). Alfalfa is not a preferred nectar or pollen source for many pollinators. If other flowering plants are available, these are frequently preferred, so alfalfa seed growers must place hives and manage pollination carefully in seed fields to accomplish cross pollination (Rincker et al., 1988). Conditions of plentiful and active pollinators may occur in some situations, but are not necessarily common in alfalfa hay fields.

c. **Probability of Pollen Movement between fields.** If flowering is occurring, and pollinators are present, the probability that pollen will move from one field to another must be considered. Pollen movement is NOT the same as gene transfer (Mueller, 2004), which requires the additional steps of fertilization and seed production (e and f). Most pollen movement occurs within fields given the close proximity of neighboring plants to the pollinators, and transfer from field to field is a small percentage of pollen movement. The most effective pollination is accomplished within 90 meter radius of a hive (Rincker et al., 1988). The probability of pollen movement will depend upon factors such as wind direction, pollinator activity, and feral alfalfa which may act as a

'bridge' between fields (Figure 1). Control of feral alfalfa around RR fields may be an important step to control the unwanted movement of pollen around these fields. Since the vast majority of pollen movement is within fields, only some fraction of pollen movement would have the potential to cause gene movement from field to field.

d. **Neighboring Field must 'nick' with the first field.** The probability of pollen flow depends upon two fields flowering substantially at the same time. Cutting schedule, variety, and other factors may influence the 'nicking' or convergence of flowering time between two fields. Since pollen has a very short life (hours or days), two fields must flower at roughly the same time to allow gene transfer.

e. **Probability of Pollination, Fertilization of flower.** Once pollinators are determined to have transferred pollen from one field to another, they must land on and trip flowers to deliver the pollen grains. Alfalfa requires floret tripping by insects, delivery of pollen from another plant, the pollen must embed on the stigma, grow a pollen tube through the style, resulting in fertilization of ovule (Viands et al., 1988). This process takes 24-32 hours. The fertilization of the ovule would result in gene transfer, but not all pollen transferred results in gene transfer, due to failure to fertilize the ovule or death of pollen cells.

f. **Probability of Seed Maturation and Production.** For gene transfer to be accomplished in hay crops, several additional

steps are required after pollen flow. Fertilized embryos must then mature into seed in order for gene transfer to have an impact upon the reproduction of the plant. Seed maturation generally occurs several months after mid bloom flowering, which occurs about 35-50 days after regrowth or emergence (Rickner, et al., 1988). Since forage harvests generally occur 28-32 days after regrowth in most areas, seed maturation from cross-pollinated flowers is rare, and not a normal consequence of forage production. However, seed production can occur on a very small number of plants under the following conditions: occasional unharvested stems which are allowed to continue growing past harvest in a field, very late harvested hay, and hay grown under intense heat conditions, such as the Imperial Valley of California. Flowering and seed maturation is more rapid under hot and droughty conditions than under well watered conditions. However full seed maturation in alfalfa hay fields should be considered unusual in hay production, and occurs infrequently, and only under specific conditions.

g. **Probability that Seed Falls to the Ground and Germinates.** Seed production itself is not sufficient to accomplish gene transfer from forage crop to forage crop. Most of the occasional seeds produced in hay fields are removed at harvest. However, for AP seed to produce 'adventitious presence' in a neighboring hay crop, it must fall to the ground, germinate and produce a plant. With the normal practice of harvesting every 28 days, all above-ground

plant parts to about 2" height are generally removed. This usually results in the removal of whatever flowers and seeds are produced—and the product is fed to livestock. However, the probability that the small amount seed that remains might germinate must be considered. This seed must have sufficient moisture and coverage on the soil surface to be able to germinate in an already-established alfalfa stand. Growers in many areas have tried deliberately overseeding alfalfa into existing alfalfa stands using grain drills, a practice that is not widely recommended (Canevari et al., 2001). Usually it requires some tillage (harrowing) in the existing stand to provide the seeds with a favorable environment for germination. However, even with tillage more often than not, the result is failure. Surface-seeding onto unprepared ground in existing alfalfa stands is even less likely to succeed. Growers who have tried this have often been frustrated by lack of germination due to competition, poor seedbed, and allelopathy of the existing plants in the stand. Given the general lack of success in deliberately seeding alfalfa into existing stands, it is not likely that the few AP seeds falling on the hard soil surface would result in plants.

h. **Probability of Survival of New AP Recruits.** A germinating seedling in an existing alfalfa stand must then survive the intense competition from neighboring alfalfa plants and weeds sufficient to become established. In order for AP presence to be detected, it must contribute to the forage yield of the crop. Alfalfa is a very

> weak seedling for several months of its early growth, and does not survive well under intense competition from either weeds or existing alfalfa plants. Growers who have attempted to 'overseed' alfalfa into existing alfalfa stands have frequently been disappointed at not only germination, but the survival of the plants that do somehow manage to germinate and grow (Canevari et al., 2001).

The combination of frequent harvests, lack of significant flowering, lack of seed production, poor soil conditions for germinating seedlings, the highly competitive and allelopathic nature of alfalfa which prevents ready germination of alfalfa seeds in existing fields would prevent virtually all gene transfer from occurring between alfalfa hay fields.

Estimating the limits to gene flow in alfalfa hay. In alfalfa **seed** fields the gene flow is estimated at approximately 1.5% at 500-900 feet for both honeybees and leafcutter bees according to field studies. This is in situations where flowering is encouraged, pollinators are placed, and seed maturation is accomplished (Teuber et al., 2004; Van Dynze et al., 2004). This may be considered an 'upper limit' for alfalfa hay fields, to which the 'environmental filters' listed above should be applied. Thus, the probability of gene movement in hay fields would be reduced significantly from this number if little simultaneous flowering occurred, pollinators were few, the crop is harvested before significant flowering, seeds are removed during harvest, and the conditions for germination and survival of the few volunteer seedlings are not favorable. Although these probabilities are not known with precision, it is clear that, the probabilities for gene transfer in hay fields

under normal conditions would be very small, likely far less than 0.01% AP from this source under most conditions. The potential may be higher in the very hot regions, such as the Imperial Valley, where alfalfa flowers profusely at 28 days, or in situations where alfalfa is harvested very late. However, the highest probability of AP presence in hay fields is likely to originate from AP presence in seed, not transfer from field to field. Thus, excess care should be taken in purchase of certified seed for those growers interested in sensitive markets.

4) Control Feral Alfalfa

Feral (wild) alfalfa is alfalfa that was not intentionally planted and typically occurs along ditch banks or roadsides and remains unharvested. Feral alfalfa is common feature of agricultural regions where alfalfa is grown. Its origin is not known, but could be from older plantings by highway departments, spilled seed, small amounts of seed from hay, or movement by birds. Since feral alfalfa is more likely to flower and set seed, and feral alfalfa may act as a 'bridge' for pollinators between distant fields, control of feral alfalfa is prudent method to prevent movement of genes between hay fields.

5) Identification of Biotech-free Alfalfa Hay

The coexistence of biotech and non-biotech alfalfa will require a higher level of awareness of crop identity for products destined for sensitive markets. This may require some simple identification steps for hay lots to assure that hay lots are not mixed, but also careful filing of records of during stand establishment (seed tags) that indicates that conventional varieties were sown. This is currently practiced on commercial hay farms anyway—but the presence of biotech alfalfa will

increase the need for crop identity for those sensitive markets.

The introduction of the first biotech trait in alfalfa may actually sharpen or increase the demand for biotech-free hay, perhaps even leading to greater market identification and value for organic or biotech-free hay. This remains to be seen, but there may be incentives for this greater identification to the grower. Organic growers have a process by which they identify and document organic hay anyway, and so this does not entail any greater paperwork on their part, other than to specify that the alfalfa is free of biotech traits. Larger exporters generally have methods of identification, and since contracts frequently require biotech-free crops for export, this will likely become a component of market identification. Test kits (discussed below) should enable further confirmation of lots and identification of fields as to their origin.

6) Prevent Mixing of Hay Lots.

A 'lot' for forage quality testing purposes is defined as a stack from the same field, same cutting, less than 200 tons, with identification as to farm and field and cutting (Putnam, 2002). There is no reason not to utilize this definition for biotech or 'biotech free' identification.

It is common sense that those wishing to sell into sensitive markets must take steps to prevent the mixing of haystacks, to maintain identity, and to assure customers of that identity through the harvesting, storage and transport process. The use of colored baling twine may be helpful in assisting growers in market identification, but growers may also want to develop their own methods of preserving identification.

7) Understand the sensitivities and tolerances of the Market

Given that the food crops in Japan require labeling if over 5% GE presence in **food crops** (over 0.9% in Europe), these very small probabilities (e.g. less than 0.01%) of Adventitious Presence in hay (**feed crops**) should not present difficulties for buyers in terms of market identity. Europe has adapted a tolerance of 0.5% for AP in foods. Logically, the tolerance for feed crops should not be greater than for food crops. According to USDA, unintentional presence of biotech traits will not result in loss of organic status. For organic producers, the very small potential estimated above for AP in alfalfa hay should not ordinarily present significant worries for their markets for feed crops. This level of risk of AP originating from neighboring hay crops is likely to be on the same order of magnitude to the risk of using any non-organic practice (spraying, fertilizing) in non-organic fields which are near organic fields. In both cases, some caution should be used to prevent influence between neighboring fields, but organic growers have coexisted with non-organic growers for decades, and methods have been developed to prevent unwanted influence of non-organic practices on organic fields or visa-versa (keep in mind that there is also risk from organic practices, if weeds are not controlled in neighboring fields).

There is no reason to think that coexistence of GE crops in regions where non-GE crops are desired cannot be successfully managed under most situations. Exceptions to this may be situations where seed production is occurring in close proximity to hay production, and flowering and seed production is early

and prolific due to excessive heat, such as the Imperial Valley of California. Growers should be aware of the conditions which facilitate gene movement (abundant flowering, seed production, good germination conditions), and take steps to limit the possibility of gene flow and market identification to prevent mixing of seed or hay products.

8) Testing for Adventitious Presence in hay.

Testing of hay lots is the final step to confirm that hay lots either contain, or do not contain, biotech traits. Procedures to measure the presence of AP in shipments of grain, for the purposes of market identification of biotech traits in crops have been developed, and now are routine for corn, soybean, and other crops. 'Test kits' have been developed by several companies for grain handlers, marketers and farmers to manage GMO traits in markets (e.g. Envirologix Co. htto://www.envirologix.com/ and Strategic Diagnostics (http://www.sdix.com/) and are now (November, 2005) available for alfalfa hay and fresh leaves.

These simple tests (Figure 2) can be performed in a lab during normal lab testing for quality, in a clean room, or even in the field. These are commercially available at this point in time for measuring AP presence in hay. These test strips detect the presence of the protein marker produced by the insertion of the Roundup-resistance gene. Fresh leaves, unground hay, and ground hay tests (for testing of routine cored hay samples by commercial laboratories) should be available. These are currently under testing by UC and others. These tests should enable growers to confirm the lack of presence of biotech traits in their hays destined for sensitive markets, and provide assurances to buyers as to the stewardship of biotech-

free hay for organic, export, or other markets. The recommendations for use of these test strips, sampling and analysis procedures should likely be completed by early 2006.

Those testing for any substance, such as an unwanted gene product, in a food product must wrestle with the issue of tolerance. There are analytical tolerances (limits of detection), and practical tolerances (due to the possibility of contamination of samples in grinders, the efficiency with which the protein is extracted from samples, and other technical factors), and commercial tolerances (what is accepted by markets). Given that the threshold for tolerance of a GMO trait in food products and grain is approximately 5%, it is not likely that tolerances for feed products to be fed to animals will be higher than this, but different markets may have differing views. A tolerance of zero is impractical for testing of hay production systems, since just dust on the fingers of the sampler, tiny flecks in a grinder, or just analytical variation could result in a false positive reading for otherwise biotech free-alfalfa hay.

SUMMARY

The majority of markets for alfalfa are not likely to be highly sensitive to the presence of a biotech trait, with the notable exception of organic producers, export producers, and some horse owners. Both organic and export markets will demand biotech-free alfalfa, at least currently. I estimate the percentage of alfalfa production sensitive to the presence of a biotech trait to be less than 3-5%, given current utilization patterns, although that may change as the trait is introduced, Methods to enable the coexistence of biotech and biotech-free alfalfa production and marketing in regions where both types will be grown are necessary.

The possibilities of genetic transfer between biotech and non-biotech alfalfa hay fields are very small—orders of magnitude smaller than the possibility of genetic transfer between seed fields. Environmental 'filters' which prevent significant cross-pollination, seed production, seed germination, and survival of volunteer plants in hay fields makes gene transfer highly improbable. Hay fields are managed to minimize flowering, seed production and volunteer plants whereas the opposite is true for seed-producing crops. Exceptions to this may include very late harvested hay, and excessive flowering due to conditions of excessive heat such as the Imperial Valley of California. Growers can lower the possibility of adventitious presence of a biotech trait even further by selecting certified seed from a reputable company, harvesting before significant bloom, and being especially aware of conditions that enhance flowering (heat, drought, late cutting) and preventing seedling recruitment and survival. Control of feral alfalfa in areas near GE fields may improve the containment of pollen movement. Practices which enable preservation of identity of crop origin through careful hay lot identification and management, along with testing of hay lots will improve confidence of buyers and sellers of non-biotech alfalfa into sensitive markets. If growers follow good management procedures, biotech and non-biotech alfalfa hay crops should be able to coexist in the same region or on same farm while maintaining trait purity and identity for use in markets sensitive to biotech traits.

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THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, vs. MIKE JOHANNS, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE Intervenor-Defendants.	) Case No. C-06-1075 CRB) **DECLARATION OF CHARLES BENBROOK IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION**) Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

I, Charles M. Benbrook, do hereby declare as follows:

1. I have personal knowledge of the technology and issues at the heart of this litigation and could competently testify if called as a witness.

* * *

11. I have reviewed the "Direct Testimony of Timothy J. Nantell Regarding Permanent Relief" and have been asked by counsel for plaintiffs to assess the assumptions, analytical methods, and data used by Professor Nantell. In addition, I have been asked to

project the economic impacts of Roundup Ready (RR) alfalfa on the organic food industry, if commercial plantings were to again be allowed.

12. Professor Nantell projects that the injunction will impose aggregate impacts of $225,000,000, assuming the injunction is lifted in time for commercial plantings to begin in the fall of 2009. Professor Nantell attributes the majority of these costs—$205 million, or 91%—to impacts on forage growers, i.e. lost net farm income.

13. A "Report of Timothy J. Nantell" is identified as Exhibit A and is attached to the Professor's Direct Testimony. This exhibit sets forth the basis of the impact estimate noted above. Unless otherwise noted, all comments herein address provisions in the Nantell Report.

14. Point 5 (page 2) in the Nantell Report sets forth critical assumptions underlying his estimates. These assumptions include that the injunction will be lifted in 2009; that growers with RR alfalfa already planted may harvest and utilize the crop; and, that seed producers under contract to produce RR seed may harvest and stockpile the seed.

15. These assumptions, and data on alfalfa production costs and returns, were incorporated by Professor Nantell into a cash-flow model typical of those used by farmers to estimate the profitability of a given business enterprise, in this case, the planting of a field to RR alfalfa. Impacts are also projected at each stage of the supply chain, beginning with impacts on seed growers and Forage Genetics, Inc. (FGI), and then including impacts on other seed companies and dealers, and finally alfalfa farmers.

16. Point 13 in the Nantell Report states the assumption that RR alfalfa seed growers already contracted to produce RR seed for FGI, from already planted/existing stands, will harvest seed and sell it to FGI under the terms of the contract. Such a course of action makes economic sense only if one assumes that the injunction will be lifted in time for plantings to resume in 2009. This assumption is questionable on four grounds.

First, it is clearly presumptuous to assume the injunction will be lifted and that this litigation will be concluded in favor of FGI. It is equally presumptuous that the USDA will complete an Environmental Impact Statement ("EIS") by 2009, and that the EIS will conclude that Roundup Ready alfalfa may be deregulated without any harm to the environment.

Second, there is growing concern among alfalfa industry leaders regarding the loss of markets if RR alfalfa is widely planted, especially in California, which is the source of substantial alfalfa hay exports to markets in Asia that will not allow GE food or animal feeds to enter their markets.

Third, the high cost of the seed, coupled with some evidence of production problems and poor control of certain weeds (several such problems are outlined in the University of California report posted at http://anrcatalog.ucdavis.edu/pdf/8153.pdf), renders the economics of RR alfalfa largely a wash for farmers, much like the economics governing other GE, herbicide-tolerant crops.

Fourth, lingering debate over this technology, and the current litigation, has raised public and grower awareness of the probable negative environmental consequences of RR alfalfa, especially gene outflow to

non-GE varieties of alfalfa and the emergence of weeds resistant to glyphosate (including RR alfalfa, which will become a weed when it grows in areas outside farmer-fields where vegetation must be managed). This awareness may trigger more careful observation of RR alfalfa in the field, and new research, generating information that will lead the USDA to change its initial judgment regarding the technology. Even if USDA completes an EIS, and again deregulates RR alfalfa for commercial use, market opposition may build fast enough to dramatically reduce the acreage ultimately planted.

17. RR alfalfa seed growers under contract to FGI could instead be directed by FGI to harvest high quality hay from their plantings, which would maximize the non-seed income from the plantings and prevent any substantial risk of gene flow (since the plants would be cut prior to flowering; alfalfa protein content is highest just prior to flowering). FGI could then pay their contract growers the relatively modest difference between projected seed income and income from high-quality hay sales.

18. Professor Nantell assumes in his model that the RR alfalfa seed that is harvested in 2007 and 2008 will be needed to meet growing demand in 2009. This assumption is flawed because there is no way of knowing how rapidly demand will grow, or whether it will grow at all, given the marginal economics of the technology for the average grower.

* * *

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007 in Enterprise, Oregon.

_____/s/_____
Charles M. Benbrook, PhD

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, vs. MIKE JOHANNS, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE Intervenor-Defendants.	) Case No. C06-1075 CRB **DECLARATION OF JIM BRIGGS IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION**) Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

I, Jim Briggs, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am a third generation farmer based in Marsing, Idaho. I have been an Alfalfa seed grower in Idaho since 1987. I average about 150 acres of Alfalfa seed production each year.

3. I am a member of the Idaho Alfalfa & Clover Seed Growers Commission, a statwide organization created to improve the alfalfa production and to expand the market for alfalfa and clover seed grown in the state of Idaho. I also serve as an advisor on the Alfalfa

Seed Advisory Board for the Idaho Crop Improvement Association, which gives recommendations to the Idaho Crop Improvement Association Board of Directors on matters related to Alfalfa seed.

4. I currently have a contract to grow non-genetically engineered seed. My contract contains a clause limiting contamination from Roundup Ready traits to 1% contamination.

5. In 2006, Idaho had over 13,347 acres of certified alfalfa seed acres produced in the state and over the last 10 years it has been as high as 35,000 annual certified acres. Idaho is known to be the best area to produce Alfalfa seed and can be based on the fact that most the major Alfalfa seed warehouses are based in the Treasure Valley. Such company's include Forage Genetics, Pioneer Hi-Bred, Dairyland Seeds, Allied seed, Target seed, Price and Sons, Sage Acres, and Vince Holtz Seeds.

6. The potential contamination of my alfalfa seed crop with the Roundup Ready trait is highly probable because alfalfa is a perennial crop which is pollinated by bees. Many bees can pollinate alfalfa seed, including bee species ranging from alkali bees, leaf cutter bees, honey bees, bumble bees, and other natural pollinators.

7. When Roundup Ready alfalfa technology was first introduced and being regulated by USDA in the Treasure Valley, myself and other growers asked Forage Genetics to include growers in the deregulation process. They told me and my fellow alfalfa growers that there was nothing we could do and that they would take care of the matter. Forage Genetics told us that their research showed that 900 feet was an adequate distance for "minimal contamination." I have now learned from "grow out" tests of seed lots from

Dairyland seed in 2006, that the contamination is higher than expected at distances of at least 1.5 miles.

8. The science on genetic contamination also shows that current isolation distances are inadequate. I have read a study funded by Forage Genetics, and prepared by Mr. Bob Hammon from Colorado State University, who performed a pollen flow study in 2006, indicating that biological contamination can occur at 3.8% at 1.7 miles. Myself and other alfalfa growers obtained the Hammon study at the Northwest Alfalfa seed growers meeting in Las Vegas on January 22, 2007. The presentation was given by Mr. Hammon and we later obtained a copy of the PowerPoint presentation from Mr. Hammons on a thumb drive. Attached is a trued and correct copy of the Hammon study as Exhibit A.

9. I have repeatedly asked Forage Genetics about contamination issues from hay fields. Mark McCaslin, President of Forage Genetics, told me and other growers that contamination may not occur if managed properly, and that it would not be an issue. As an experienced alfalfa seed and hay grower of many years, I know this statement is false, because many variables can create conditions that will result in hay plants going into bloom, such as not cutting edges of fields, poor weather, alfalfa growing in waste ditches that cannot be reached and cut, and the timing of custom cutting. Custom cutting is the hiring of a person to come in and cut hay fields at your requested time. Growers often cannot control the custom cutting schedule because of the timing of their request, the numbers of other requests, and the number of acres a custom cutter has to cut before he can fulfill your request. When alfalfa hay plants bloom accidentally,

the pollen can be taken by bees to contaminate other fields. Alfalfa hay fields that are planted during the same season will have overlapping bloom cycles, creating a very real possibility of cross contamination. Additionally, in Idaho there are no restrictions on planting hay and seed fields next to each other. (See web site http://www.idahocrop.com/StandardDocs /Alfalfa-R&R.pdf.) Monsanto is required to collect GPS coordinates for the fields, however they do not release the coordinates to the public.

* * *

12. On March 15 2006, I attended an Idaho Crop Association Alfalfa Advisory annual meeting, at the Library Coffee House in Meridian, Idaho. During this meeting, a representative of Forage Genetics named Jose Arias made a motion to reduce the Roundup Ready isolation distance from 900 feet to 165 feet (the standard for conventional seed.) This motion was soundly defeated by the stunned committee members because Forage Genetics failed to offer sound evidence to the committee that addressed the committee's concerns about Roundup Ready contamination.

13. On November 2, 2006, I attended an Idaho Crop Improvement Association meeting in Boise, Idaho. During this meeting, Greg Lowry, Executive Vice President of the Idaho Crop Improvement Association, gave an update in which he described that Dairyland Seed, a major seed warehouse in Idaho, had detected biological contamination with the Roundup Ready gene in its non-Roundup Ready alfalfa in 9 Montana fields, 1 Wyoming field, and 1 Idaho, even where the 900 foot isolation distances were used. Minutes from this meeting are attached as Exhibit B.

14. At the November 2, 2006 Idaho Crop Improvement Association meeting in Boise, Idaho, Doug Gross, a representative of Dairyland Seed, one of the largest alfalfa seed producers in the Idaho, presented information about biological contamination incidents with Roundup Ready alfalfa genes of several of their non-genetically engineered seed lots, including foundation seed lots. Foundation seed is pure seed stock used to propagate more seed for sale. During that meeting it was discussed that seed lots were contaminated. Doug Gross from Dairyland stated that they performed the litmus tests on the seed and after positive tests, sent samples to an independent lab for "grow out" tests to positively determine the percentage of contamination. A grow out test is a test for biological contamination where a specific amount of alfalfa seed is placed in a tray, germinated, and then sprayed with Roundup. Plants that survive the spraying of the Roundup herbicide are then counted to determine the percentage of Roundup herbicide resistance plants. Dairyland Seed's grow out tests indicated that 11 lots tested positive from a trace to .9 percent contamination at distances up to 1.5 miles.

15. At the November 2, 2006 Idaho Crop Improvement Association meeting in Boise, Idaho, I heard Jose Arias, a representative from Forage Genetics, state that the one lot from Montana at .9 percent could have been contamination from a combine according to the information that they had received. I know for a fact that Forage Genetics knows about the Dairyland contamination events because two representatives from Forage Genetics, Jose Arias and Ken McIntyre, were at the meeting.

16. On November 1, 2006, Steven A. Strachota, President of Dairyland Seed Co., Inc., wrote a letter to Gregory Lowry, Executive Vice President of Idaho Crop Improvement Association, indicating that at least 11 of Dairlyland's non-Roundup Ready seed fields in Montana, Wyoming, and Idaho were contaminated by Roundup Ready alfalfa at distances ranging from 950 feet to 1.5 miles. Doug Gross of Dairyland Seed Co. gave me a copy of this letter after I asked him for this letter in order to inform Idaho growers of the contamination issue with the 2006 seed crop. The hand written numbers on this letter are my handwriting, where I numbered the contamination distances from 1 (least) to 9 (most). A true and correct copy of this letter is attached hereto as Exhibit C.

17. In December, 2006, I wrote and sent out a letter to the members of the Idaho Alfalfa & Clover Seed Growers Association. This letter was edited by Mike Nichols, member of the Board of Directors for the Idaho Alfalfa and Clover Seed Commission and Ron Platt, who is the current President of the Idaho Alfalfa and Clover Seed Growers Association. This letter was then reviewed and approved by the Idaho Alfalfa & Clover Seed Growers Association for distribution. This letter explains to the Idaho growers that the independent testing agency Midwest Seed Lab confirmed that eleven lots of non-Roundup Ready alfalfa seed tested positive for the Roundup Ready gene in fields in Montana, Wyoming, and Idaho at distances ranging from 950 feet to 1.5 miles. I based this letter on data that was presented to the Idaho Crop Improvement Association and research data from Forage Genetics that I obtained from Forage Genetics'

website. A true and correct copy of this letter is attached hereto as Exhibit D.

18. On January 16, 2007, I attended the Idaho Alfalfa & Clover Seed Growers Association meeting at the Hampton Inn, in Nampa, Idaho. During a round table discussion, I heard Doug Gross of Dairyland Seed Co. state that Dairyland had confirmed that 16 lots of non-Roundup Ready seed had tested positive for Roundup Ready contamination. Present at the meeting were Jose Arias, and Peter Reisen from Forage Genetics.

19. Based on the evidence given to me by Doug Gross of Dairyland Seed, the research conducted by Forage Genetics, and the research of Mr. Hammon, and based on my years of experience as an alfalfa seed and hay grower, in my opinion contamination of non-genetically engineered alfalfa with Roundup Ready alfalfa through pollen drift and other mechanisms poses a very real and serious threat to maintaining alfalfa seed stocks free of genetically engineered genes. Given all of this evidence that biological contamination has in fact occurred in seed fields in Idaho, I am very concerned about contamination of my fields. If my fields are contaminated, I would suffer great economic harm.

20. One of the companies I grow for have a contract for non-Roundup Ready alfalfa seed that enumerates a 1% limit on adventitious presence of Roundup Ready alfalfa gene in the seed. If my seeds were to be contaminated beyond 1%, the company has the option to reject the seed or negotiate a lower price. If a seed lot were to turn up positive, I would likely have to destroy the seed crop, thus voiding the remaining years of the contract, which could be up to

three years. If my seeds were contaminated during the first year, the company may not want take the chance of any more contamination off of that field, therefore I would have to remove that stand of alfalfa, even though it could remain for several more years. Annually, I could lose approximately $1,300/acre on the affected fields. In 2006 we grew 75 acres of alfalfa seed with contracts containing Roundup Ready clauses. If these 75 acres were to be contaminated, I could be harmed up to $97,000.00 annually. If the contamination came from a hay field next to my seed field, that field may have to be out of seed production until the Roundup Ready hay field is plowed out. In my farming operation, these fields would be rotated to wheat, which is much less profitable the alfalfa seed.

21. I my opinion, the planting of any more Roundup Ready Alfalfa seed must be stopped until these questions are reviewed in more detail. The continued risk of contamination must be halted until the USDA, Monsanto, and Forage Genetics determine how Roundup Ready alfalfa can be introduced into the United States without contaminating all non-Roundup Ready alfalfa. Alfalfa seed is the second largest seed crop in the state of Idaho, with a cash value to growers of over $16 million dollar, according to the Idaho Seed Indemnity Fund. Idaho alfalfa growers will likely be damaged if contamination becomes widespread, destroying our reputation as the best Alfalfa seed production area.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 3, 2007 in Marsing, Idaho.

_____/s/_____
Jim Briggs

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, vs. MIKE JOHANNS, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE Intervenor-Defendants.	Case No. C-06-1075 CRB **DECLARATION OF ERNEST JOHNSON IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION** Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

I, Ernest Johnson, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I live at 9265 Paradise Valley Road, Chinook, MT 59523. I am currently President of the Montana Alfalfa Seed Growers Association. This is my third term as President.

3. My father and I started raising Alfalfa seed in 1981 on 20 acres. We expanded our seed acres in 1982, which included contracting with Allied Seed Company.

This transaction provided an additional 30 acres to our farm, and we also hired a custom harvester to combine the crop.

4. In 1984, we purchased a John Deere 95 Combine to harvest our crop. Several years later we obtained another JD95 and have used both of these machines since then and this includes harvesting our 2006 crop.

5. We have always used leafcutter bees to aid in the pollination process of raising alfalfa seed. In 1981 we hired a company to bring bees onto our fields to pollinate our crop. In 1982 we purchased bees from Canada and every year since that time, we have used our own bees to increase the crop. Over the last several years we have increased our acreage of alfalfa seed which has required us to purchase more bees each year. We obtain a positive return on our bees most every year; we get more bees back than we put out on the fields. We purchase new bees from Canada each year, nest these bees in drilled boards. We then sell the wood hives, filled with bee larvae, to two seed producers in the Boise Idaho Valley area.

6. The alfalfa seed industry in Montana is relatively small (about 35 farmers in our state association), but the income from alfalfa seed production accounts for more than 50% of the profit on our farm.

7. Roundup Ready alfalfa became legal for sale in later summer of 2005. Roundup Ready alfalfa has been planted as close as 2 miles from my fields of traditional alfalfa seed production. I understand that under the agreed upon management practices the participating hay farmers agree to not produce alfalfa seed from these stands or allow the fields to produce significant

amounts of blossoms. I am very concerned about the contamination coming in onto my fields because historically the weather of the last week of June, when hay is to be cut, can be very rainy. This prevents the harvest of alfalfa hay - the alfalfa continues to grow and flower and the contamination potential continues to proliferate. When the rains stop and the weather dries, the bees have already spread the pollen to my alfalfa seed fields 2 miles down the road.

8. At the Northwest Seed Growers meeting in January 22-23 of 2007, in Las Vegas, Nevada, we learned of the Bob Hammon study that was commissioned by Forage Genetics to determine how far bees would transfer the Roundup Ready pollen. The results indicated that the pollen was transferred up to 1.7 miles. When I asked Mr. Hammon "how far he would say that a field would have to be away from a roundup ready field and not be potentially contaminated?" Mr. Hammon replied that it would have to be 5 miles away.

9. At the Montana Alfalfa Seed Growers Association meeting on February 15, 2007, Billings, Montana, Mike Huff, a field representative of Dairlyland Seed Col, told us of 16 different lots of traditional Dairyland alfalfa seed that had become contaminated. Mike Huff also informed us of contamination of a Dairyland foundation seed field.

10. At the same Montana Alfalfa Growers Association meeting on February 15, 2007, Rod Leafdale stated that a contamination from a neighboring farmer's field results in a liability issue between the two farmers, and forage Genetics has no liability in that situation. I am greatly concerned that

Forage Genetics is assuming no responsibility for damage to farmers.

11. I produce certified public alfalfa seed varieties, common seed varieties, and proprietary varieties for one of the major seed companies. If the certified public varieties became contaminated with GMO pollen, I cannot receive the "certified" stamp of approval from the Montana certifying agency. Thus this seed becomes non-certified and unmarketable. If my farm becomes contaminated I will lose revenue from 20,000 pounds per year at approximately $1.50/LB for a total of $30,000.00. This economic harm would continue annually because this contamination would persist in my seed stocks.

12. I grow 130 acres of certified non-Roundup Ready alfalfa seed under contract for two major companies, Dairyland Seeds, Inc. and Northstar Seeds. Contamination of this production would result in the loss of $117,000 per year. (130 acres x 750 pounds of seed per acre x $1.20 per pound of seed.)

13. A contamination of my seed fields would also be a deadly blow to my bee sales. Leafcutter bees build their nests out of alfalfa leaf pieces and alfalfa pollen and nectar. The roundup ready gene would become an integral part of the bees. Contaminated bees could not be used on traditional alfalfa without contaminating that field also. Estimated annual loss on bee sales = approximately $28,000 (sale of bees in March of 2007 = $28,000).

14. My total annual loss if my fields were contaminated with Roundup Ready alfalfa would be $175,000.000 ($28,000 + $117,000 + $30,000).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 3, 2007 in Chinook, Montana

_____/s/_____

Ernest Johnson

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, Inc., *et al.*, Plaintiffs, v. MIKE JOHANNS, *et al.* Defendants. and MONSANTO COMPANY, FORAGE GENETICS, INC. JOHN GROVER, DANIEL MEDEROS, and MARK WATTE, Intervenor-Defendants.	No. C-06-1075 CRB **THIRD DECLARATION OF PAULETTE PIERSON, PH.D. IN SUPPORT OF MONSANTO COMPANY'S SURREPLY ON PROPOSED PERMANENT INJUNCTION** Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles Breyer

THIRD DECLARATION OF PAULETTE PIERSON, PH.D. IN SUPPORT OF MONSANTO COMPANY'S SURREPLY ON PROPOSED PERMANENT INJUNCTION

I, Paulette Pierson, Ph.D. declare as follows:

1. I am the Technology Development Manager for Roundup Ready®[1] Alfalfa and Roundup Ready Sugarbeet for the Monsanto Company ("Monsanto"), a position I have held since 2005. Monsanto is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality. A true and correct copy of my curriculum vitae is attached as Exhibit A to the declaration I have submitted previously in this matter on March 2, 2007 ("Pierson Decl. I").

2. In addition to Pierson Declaration I, I also submitted a declaration on March 23, 2007 in support of Monsanto's Memorandum on Proposed Permanent Injunction ("Pierson Decl. II"). I submit this declaration to respond to several issues raised by Plaintiffs in their April 6, 2007 filings.

3. I have personal knowledge of the matters referred to herein and if called upon to testify could and would testify truthfully thereto. Below, I will address the following declarations submitted by Plaintiffs:

- General observations on all of Plaintiffs' declaration, including:
  - —Hay-to-hay transmission of the Roundup Ready trait (¶¶ 5-9);
  - —Gene contamination in crops other than alfalfa (¶¶ 10-14);
  - —Potential gene flow will not irreversibly harm the environment (¶¶ 15-18); and
  - —The Hammon Study (¶ 19).

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1 ®Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

- Declaration of Doug Gurian-Sherman relating to gene flow, including:
  - —Dr. Gurian-Sherman's qualifications (¶¶ 21-23);
  - —Crops other than alfalfa (¶¶ 24-30); and
  - —Dr. Gurian-Sherman's incorrect interpretation of the Teuber and Hammon studies (¶¶ 31-33).
- Declaration of Allison Snow (¶¶ 34-40);
- Declaration of Clinton Shock (¶¶ 41-45);
- Declaration of Jim Briggs (¶¶ 46-48);
- Declaration of Charles Benbrook (¶¶ 49-51); and
- Declaration of Doug Gurian-Sherman relating to weed resistance (¶¶ 52-97), including:
  - —Roundup Ready alfalfa differs materially from Roundup Ready row crops (¶¶ 60-70);
  - —Glyphosate use on Roundup Ready alfalfa is de minimis compared with overall use (¶¶ 71-72);
  - —Stewardship measures and promotion of those measures have developed considerably (¶¶ 73-77);
  - —Effects during time frame for completion of EIS (¶¶ 78-79);
  - —Dr. Gurian-Sherman's criticisms of the proposed stewardship measures are overstated (¶¶ 80-95); and
  - —Weed resistance will not irreversibly harm farmers or the environment (¶¶ 96- 97).

GENERAL OBSERVATIONS

4. After reviewing the various declarations submitted by Plaintiffs on April 6, 2007, there are several overall critiques that become clear.

Hay-To-Hay Transmission Of The Roundup Ready Trait

5. First, the Plaintiffs do not present any evidence to refute the conclusion drawn through my prior declaration, and in the declarations and direct testimony of Drs. Putnam, Undersander, and Hoffman, that hay-to-hay transmission of the Roundup Ready trait will be an exceptionally rare event—with a near zero probability.

6. Hay-to-seed transmission of the Roundup Ready trait to conventional alfalfa seed production will also be extremely limited. As has been stated in my prior declaration and in the declarations and direct testimony of Putnam and Tueber (Tueber, Ex. D) gene flow potential was found to be approximately 0.25% from a blooming alfalfa hay field (20% bloom) to an alfalfa seed crop at 165 feet and gene flow was rarely detected (0.00 to 0.05%) at distances greater than 350 feet from the source.

7. Plaintiffs' filings focus almost entirely on transmission between seed crops and not from forage to forage. For example, Dr. Shock's declaration focuses almost entirely on concerns for trait movement from seed production fields. Although he briefly addresses the potential for hay-to-seed movement (Shock Decl. ¶ 9), Dr. Shock does not dispute that potential for hay-to-hay movement approaches zero. Similarly, Dr. Snow (Snow Decl. ¶ 6) does not identify hay-to-hay transmission as a route for spread of transgenes from Roundup Ready alfalfa to conventional alfalfa. Likewise, concerns raised in the Briggs declaration and Cal/West letter relate solely to the movement of the Roundup Ready trait to conventional alfalfa seed production. Dr. Gurian-Sherman makes the incomplete

argument (Gurian-Sherman Decl. ¶ 69) that Dr. Putnam's explanation of the steps and estimation of the probability of each of these steps in transmission of the Roundup Ready trait to conventional and organic hay and its contribution to the hay are arbitrary. Dr. Putnam, a world-renowned expert in alfalfa production, very clearly outlined the steps in the process for the trait from Roundup Ready alfalfa to move to, contribute to and be detectable in organic or conventional hay production. Perhaps Dr. Gurian-Sherman misunderstood that these steps are similar to links in a chain. All steps must be successful for the Roundup Ready trait to move to, contribute to and be detected in organic or conventional hay. If any one step is unsuccessful the chain breaks and Roundup Ready alfalfa will not be present and therefore not detectable in an organic or conventional hay field. The probability of each step may vary with some being more likely but unless the probability of each step nears 100%, which is highly unlikely for most steps or links in the chain, the probability of successful trait movement and establishment becomes an extremely low number as Dr. Putnam asserts. (*See* Mar. 23, 2007 Putnam Direct Test. at 11:3-11:19.)

8. The probability of hay-to-hay movement of the Roundup Ready alfalfa approaches zero, therefore, production of Roundup Ready alfalfa hay in proximity to organic or conventional hay poses virtually no possibility of harm to conventional or organic hay grower. This exceptionally low likelihood of hay-to-hay transmission of the Roundup Ready trait has not been disputed by Dr. Shock, Dr. Snow, Mr. Briggs or Dr. Gurian-Sherman. Nothing in Plaintiffs' submission would support any contrary conclusion.

9. Certified alfalfa seed production is almost exclusively restricted to the western U.S. Areas of California, Idaho, Wyoming, Utah, Washington, Montana, Oregon and Nevada provide the right environment, low humidity and rainfall during seed curing and harvest, to produce high quality seed. As Dr. Undersander states in his direct testimony and declaration, "*there is no significant alfalfa seed production in the eastern United States.*" (Undersander Direct Test. at 3:23-3:24 (emphasis in original).) The greater humidity east of the Missouri River increases alfalfa diseases and reduces seed quality. This area would include the Midwest and the Northeast where alfalfa is produced exclusively for forage.

Gene Contamination In Crops Other Than Alfalfa

10. Plaintiffs attempt in numerous statements to use gene contamination or adventitious presence ("AP") in crops such as soybeans, corn, and canola to suggest that there is a greater possibility of gene contamination with alfalfa. These are apples-to-oranges comparisons. Each crop is unique and has unique and specific requirements for seed production to ensure varietal purity. Seed certification organizations have found these requirements effective in maintaining the seed purity standards set by the industry consistent with accepted tolerances for AP. The conventional and organic seed industry do not require 100% varietal purity. Thus, the requirements for these crops are not specified to achieve 100% purity. Seed and varietal purity standards have been set based on the crop. Isolation and other stewardship measures have been developed specifically based on the crop's

biology and the accepted tolerance levels of AP in the crops.

a. Soybeans have a perfect flower meaning male and female flower parts are both present in the flower. Soybean is a self-pollinated crop so there is naturally almost no pollen movement between plants. For certified soybean seed production, a minimum six-foot physical isolation distance is required from another soybean variety. The field used must not have been planted to soybeans the previous year unless the previous variety has distinguishing characteristics that would allow the producer to identify the previous crop in order to remove any volunteer plants. Certified seed is required to be 99.5% true to type or pure meaning that up to 0.5% of other varieties can be present (Indiana Soybean Certification Standards).

b. Corn is a wind-pollinated, annual crop. The male (tassel) and female (ear) flower parts are separated on the plant. Corn pollen, although moved by wind, is heavy and does not travel far from the pollen source. Certification standards for corn differ from those of soybeans because of the basic differences in the reproductive biology of the two crops. Greater physical isolation distances are required for certified corn seed production. Minimum isolation of 660 feet is required between fields of yellow, dent corn and popcorn, sweet corn or colored corn. Border or buffer rows of the corn hybrid production can also be used as a pollen trap and a method of isolation. Buffer rows would be harvested and sold as feed corn rather than certified seed. Field size impacts the number of buffer rows needed with larger fields requiring fewer buffer rows. Like soybeans these standards are designed to

result in corn hybrid seed purity of 99.5%. (Indiana Certified Corn Production).

c. Canola, a crop grown for oilseed, is primarily self-pollinating but pollen movement by wind and insects, primarily honeybees, will result in some percentage of out-crossing. Like soybean, canola has a perfect flower with male and female parts in the same flower. Canola can produce hard seed and is a volunteer weed problem in crop rotations. To avoid contamination of certified seed fields, a five year period of "isolation" or rotation away from other canola, brassica or mustard crops is required before a field can be used for certified canola seed production. Isolation distances of 660 feet between certified seed production fields and other canola or mustard crop fields are required. For certified canola seed, other varieties can not represent more than of 0.25% of the seed lot. (Minnesota Certified Seed Production.)

d. Alfalfa differs from corn, soybean and canola in that the primary commodity harvested by alfalfa growers is forage and not seed or grain. Of the approximately 23 million acres of alfalfa grown in the U.S. just a little over 100,000 acres are grown for seed production. Flowering in an alfalfa hay field is limited. Alfalfa is a perennial crop that has perfect flowers that require bee pollination to produce seed. Certified conventional alfalfa seed production requires an isolation distance of 165 feet between alfalfa varieties for field sizes of five acres or more while fields smaller than five acres require double the isolation distances—330 feet. A minimum of two years must elapse between destruction of one alfalfa seed field and the planting of the field to another variety for seed

production. Certified alfalfa requires a minimum seed purity of 99% (Idaho Seed Certification Standards).

e. For production of Roundup Ready alfalfa seed the Idaho Seed Improvement Association has increased physical isolation distances to a minimum of 900 feet (for leafcutter bees) for certified seed and requires a rotation of a minimum of three years after a Roundup Ready alfalfa crop is grown before the field can be used for conventional alfalfa seed production. These additional isolation parameters were established based on scientific research results and an accepted 1% level of AP—the limit agreed upon by growers and by the industry. (*See* Gurian-Sherman Decl., Ex. O.) Note that the Government has now proposed a more significant isolation distance as a remedy in this case: 1500 feet for leafcutter bees and 3 miles for honey bees.

f. The information provided by Dairyland (attached to Mr. Briggs' and Dr. Gurian-Sherman's declarations), if true, indicates that the isolation distances being used for Dairyland growers are effective in reducing Roundup Ready off-types in conventional alfalfa to a level below the AP tolerance level specified by Dairyland itself. The attachments provide data for 11 samples of seed from Dairyland's 2006 seed production in Montana, Wyoming and Idaho. It is not clear from the data if these samples represent entire seed lots or if they are from sub-samples. Nor is there any indication of the percent of seed lots that these samples represent. Dairyland is a major alfalfa seed producer who certainly produces far more (perhaps hundreds or over 1000) lots of seed. The letter does not suggest the AP of the Roundup Ready trait is wide spread in their conventional germplasm. The only harm identified is the inability to use the

approximately 1000 lbs. of seed produced from their foundation seed field with AP of 0.2%. They fail to mention that they can indeed sell this foundation seed as certified seed, rather than use it as seed for planting certified seed production acres.

11. Temporal isolation, time rotated away from seed crop, and physical isolation, distance between seed field and other varieties, are established for crops based on the biology of the crop. There is no one standard set of certified seed production requirement for all crops. Each crop has established their isolation distances based on the biology of the plant and accepted tolerance for AP. Thus, stewardship requirements for other crops are not appropriately compared to the measures proposed in this case for alfalfa.

12. A seed producer can maintain the purity of the seed they produce by testing prior to planting and through all the stages of the seed production processing including seed movement, seed cleaning, seed storage and packaging. According to Minnesota Standards for Certified Seed Production, a seed producer "must maintain genetic purity and identity at all stages of seed production, conditioning and handling."

13. Identity preserved seed or crop production involves the grower adopting specific practices in order to produce a crop, seed, grain or forage, which meets the specific requirements of a particular buyer. Requirements for purity or identity preservation are established by the buyer who pays a premium for the identity preserved product. The requirements are agreed on between buyer and seller and it is incumbent

upon the grower to know what they can or can not promise and deliver.

14. The introduction of Roundup Ready soybeans, for example, has created an identity preserved market for conventional soybeans for export to Japan as well as the production of products such as lecithin where growers receive a premium for GE-free soybeans. The grower sets the appropriate temporal and physical isolation to ensure the specific requirements of the contract are met. This has long been the practice for corn production for the specialty market which includes popcorn and white or blue corn which are used for food products such as tortilla chips. Where buyer specifications can not be met the product may still be purchased but the price changed to compensate the buyer for additional post-harvest processing that might be required, such as additional cleaning necessary to remove yellow dent corn seeds from popcorn or blending of lots to reduce the level of a contaminant below a set threshold; at worst the product might be rejected by the buyer requiring the grower to sell the product on the commodity market at the current market price. The loss to the grower is the premium they would have received for delivering a product that met buyer specification. Rarely if ever, is the product unmarketable and total loss for the grower due to failure of identity preservation practices to reduce contamination below contract levels.

Potential Gene Flow Will Not Irreversibly Harm The Environment

15. Plaintiffs imply that vast "contamination" of organic, other non-Roundup Ready fields and the environment generally would occur if continued

Roundup Ready alfalfa planting were allowed for the next two years. This is simply not the case.

16. All of the data and evidence I am aware of, including good stewardship practices, demonstrates that the potential for gene flow is very low. If it were to occur, however, pollen flow and resulting gene flow from Roundup Ready alfalfa seed fields to conventional or organic seed or forage production fields will not result in irreversible harm to the existing field. Any potential pollen from Roundup Ready alfalfa will only affect the flower and resulting seed, and then only in the plant or plants that are recipients of the pollen. In the case of an organic or conventional hay field, the forage crop will be harvested along with any immature seed that might have potentially resulted from a rare pollination event. Likewise, pollen flow that might result in mature, viable seed formation will be removed from the conventional seed production fields when the seed is harvested. Under either scenario the organic or conventional alfalfa field will not be "changed" into a Roundup Ready alfalfa field as a result of a rare pollination event.

17. It is much akin to the development of the mule in animal breeding. Mules result from the successful mating of a female horse or mare with a male donkey. The progeny, the mule, does not change the genetic make up of the female parent or mare. She is still a horse. Similarly if pollen from a Roundup Ready alfalfa field were to be introduced into an organic or conventional alfalfa field, those biotech traits are easily removed from the field, without changing the integrity of the underlying plants. That underlying organic or conventional plant will then continue to produce

organic or conventional alfalfa in the future for the remaining life of the stand.

18. Plaintiffs' implication that the Roundup Ready alfalfa trait will spread uncontrolled like wildfire throughout a particular field or other parts of the environment is not based on fact or science. More importantly, however, even if there was evidence of "contamination" in a particular field and a farmer had a continuing concern, it is possible to remove that portion of the affected field (or all of it) by destroying the crop and starting anew with organic or conventional seed. While this may have certain financial implications for the farmer, it is important to understand that any potential "contamination" is in fact physically reversible.

The Hammon Study

19. Several of the Plaintiffs' declarations (Gurian-Sherman and Briggs) have used a report authored by Hammon, Ridderle and Franklin as evidence of the potential distance of pollen flow from Roundup Ready alfalfa seed fields. Dr. Gurian-Sherman and Mr. Briggs have extrapolated beyond the data presented by Hammon to suggest that gene flow from Roundup Ready alfalfa has been underestimated by Tueber and others. The Hammon study was not designed to estimate pollen flow potential from Roundup Ready alfalfa to another alfalfa seed field. Dr. Hammon himself has indicated that Plaintiffs' experts misused his study. (Hammon Rebuttal Test. at 3:22-4:14.) There is no data on the potential for Roundup Ready alfalfa seeds to become established outside of cultivation. These seeds still face competition from existing vegetation for moisture and sunlight. In the absence of a selective advantage of glyphosate applications it is

highly unlikely that these seeds will become established. In addition, there is no evidence that pollen flow from Roundup Ready alfalfa has resulted in feral populations of Roundup Ready alfalfa or that feral populations of Roundup Ready alfalfa will become pervasive.

DECLARATION OF DOUG GURIAN-SHERMAN RELATING TO GENE FLOW

20. I have reviewed the declaration of Doug Gurian-Sherman, which Plaintiffs submitted on April 6, 2007, in support of Plaintiffs Permanent Injunction. In this section, I will discuss Dr. Gurian-Sherman's qualifications and statements relating to gene flow. Below, following my discussion of the declarations submitted by Plaintiffs that discuss gene flow, I will address Dr. Gurian-Sherman's incorrect statements on weed resistance.

Dr. Gurian-Sherman's Qualifications

21. I have reviewed Dr. Gurian-Sherman's qualifications and experience. His training and research does not seem applicable to the issues before the Court. Dr. Gurian-Sherman is a plant pathologist by training. Plant pathology is the study of plant diseases; namely, the focus on the pathogens—bacteria and fungi—and their interactions with the plant. Agronomy is a more integrated science. Agronomy majors study basic courses botany and plant physiology but then take it to a more applied level with courses in plant pathology, soils, genetics, crop production (applied physiology) and weed science. Weed science is the study of the impact and management of weeds with chemistry and other control methods in crop production. While Dr. Gurian-Sherman may have

studied genetics and gene flow in his ecology program, it is not clear that he has the expertise necessary to opine on gene flow between alfalfa plants. He lists no research experience with alfalfa. His graduate study and publications deal with the niche area of how various bacteria can prevent plant damage from ice or frost. His post-doctoral research on the molecular genetics of rice and wheat, self-pollinated crops, does not make him an expert in alfalfa gene flow.

22. Also, Dr. Gurian-Sherman refers to several reports that he did not author on topics other than alfalfa, such as corn and soybeans. To the extent that, after reviewing these studies, Dr. Gurian-Sherman concludes that there was movement of genes for those other crops, those levels are not high and are also not relevant here. Dr. Gurian-Sherman chose to include two large documents published by the Union of Concerned Scientists as attachments to his declaration. Neither of these documents are relevant to the Roundup Ready alfalfa discussion. Questions of testing methodologies, lack of lab standardization practices and proper sample handling make the validity of the results presented in "Gone to Seed" (Gurian-Sherman Decl., Ex. G) specious. Likewise "A Growing Concern" (Gurian-Sherman Decl., Ex. H) focuses on issues and safeguards prevent movement of traits for the production pharmaceuticals or industrial chemicals in agricultural crops.

23. I will now comment on Dr. Gurian-Sherman's discussion of crops other than alfalfa to draw comparisons with alfalfa, and his incorrect interpretations of the Teuber and Hammon studies.

Crops Other Than Alfalfa

24. Dr. Gurian-Sherman comments on StarLink™ corn (Gurian-Sherman Decl. ¶ 47), Clearfield rice (*Id.* ¶ 52), and herbicide-tolerant bentgrass (*Id.* ¶ 56). Dr. Gurian-Sherman's discussion of StarLink corn, Clearfield rice, and herbicide-tolerant bentgrass is irrelevant to the discussion of Roundup Ready alfalfa. These situations involved different crops, different problems, different stewardship measures, different circumstances, and different companies. It is not appropriate scientific method to take these different scenarios and apply them here.

25. StarLink corn, the commercial name for corn hybrids containing the Cry9c protein that controlled insect feeding and damage by corn borer, was approved by the EPA for feed use only while further evaluation on its food safety was being completed. Commodity corn can find its way into many uses from animal feed to processing into food ingredients. Growers who grew StarLink corn were required to "channel" or sell their corn as feed only. Crop segregation mechanisms were not in place to isolate StarLink corn and ensure it was channeled to customers who would use it as animal feed only. Mechanical mixing of StarLink corn with other commodity corn resulted in StarLink corn ending up in trace but detectable amounts in food products including corn chips. As a result of this incident, EPA recognized that animal versus food use product channeling was not possible for commodity grains and no longer grants approvals for feed-only use of biotechnology-derived, commodity grain products with pesticidal traits. Roundup Ready Alfalfa is not a pesticidal product. It was evaluated for both food and feed safety by the FDA based on data demonstrating

that Roundup Ready alfalfa was substantially equivalent to conventional alfalfa and therefore safe for food and feed use.

26. Segregation of identity preserved grain, which is sold at a premium over commodity grain, is very successful in the U.S. We are also successful in segregating grain for export to the EU versus export to Japan or domestic use. Monsanto worked with the grain marketing industry to develop our Market Choices, a stewardship program, which identifies elevators and grain marketers that sell domestically, or to Japan and not to the EU. This helps ensure biotech grain that has full U.S. approval will not be shipped to countries where regulatory approval is still pending.

27. Alfalfa hay is easier than corn to segregate as it is packaged in bales. Most bales are large, 500 pounds or more, making it harder to mechanically mix them than corn grain. Hay is often sold directly to an end user from the grower's barn or field rather than being trucked to a central location, as corn is, again reducing the chance for mechanical mixing.

28. With regard to Clearfield Rice, on March 9, 2007, testing by APHIS confirmed the presence of trace levels of genetic material, or a transformation event designated LLRICE604, not yet approved for commercialization in Clearfield 131 (CL131) rice seed. APHIS issued emergency action notifications (EANs) to distributors of 2005, 2006 or 2007 registered or certified CL131 rice seed, and producers who are known to have received it, to stop the further distribution and planting of this seed. Additionally, APHIS is working with the rice industry to inform distributors and farmers with saved CL 131 rice seed from prior crop years that they cannot further

distribute or plant it. On March 22, 2007 a USDA press release announced the protein encoded by LLRICE604 is the same protein found in other Clearfield crops and is safe.

29. Monsanto uses a "gold standard process" when it moves a trait from the lab into the breeding step of variety development. As part of Monsanto's gold standard process, seed containing our selected event is exhaustively tested to make sure that only the event of interest is in the seed before it is passed on to a breeding group. A similar "gold standard process" was used in developing Roundup Ready alfalfa to ensure no unintended or regulated events were present in the seed used to develop Roundup Ready alfalfa varieties.

30. With regard to herbicide-tolerant bentgrass, Dr. Gurian-Sherman's comments and references are irrelevant in the discussion of pollen movement and gene flow in alfalfa. (Gurian-Sherman Decl. ¶ 56.) Bentgrass is a wind-pollinated, monocot while alfalfa is a bee-pollinated dicot plant. Differences in plant anatomy, flower type and pollination method make pollen flow studies in bentgrass an apples-to-oranges comparison in the discussion of pollen flow in alfalfa.

Dr. Gurian-Sherman's Incorrect Interpretation Of The Teuber And Hammon Studies

31. In paragraphs 57-58 of his declaration, Dr. Gurian-Sherman criticizes the Tueber study, yet these criticisms are not well founded. For a bee pollinated crop, unlike a wind-pollinated crop, there is no evidence a larger pollen source would result in more gene movement. A canola study submitted to the court by Plaintiffs (Gurian-Sherman Decl., Ex. O) found no increase in predicted gene flow between fields of conventional and GE canola ranging in size from 62 to

250 acres. In larger fields of alfalfa, bees might move simply within the same field rather than to neighboring fields. Thus, the small size of the field he selected may actually make pollen flow to another field more likely, not less likely.

32. In paragraph 65 of his declaration, Dr. Gurian-Sherman discusses "leptokurtic distribution" to suggest that the Teuber and Fitzpatrick diminishing returns data is wrong and that it is possible to have random contamination at varying distances from a pollen source. It appears Dr. Gurian-Sherman does not understand what a leptokurtic distribution looks like. "A leptokurtic distribution has a more acute 'peak' around the mean (that is, a higher probability than a normally distributed variable of values near the mean) and 'fat tails' (that is, a higher probability than a normally distributed variable of extreme values)." (http://en.wikipedia. org/wiki/Kurtosis (citing Joanes, D. N. & Gill, C. A. (1998) Comparing measures of sample skewness and kurtosis. *Journal of the Royal Statistical Society (Series D): The Statistician* 47 (1), 183-189).) Leptokurtic distributions have been observed and may predict pollen movement and gene flow for wind-pollinated species like trees but are not applicable for discussions of bee pollinated species. Dr. Gurian-Sherman cites only one data point from the Hammon study as evidence that pollen movement in alfalfa does not diminish over long distances. Mr. Hammon has pointed out that his study was designed to examine bee populations in a seed production area and not as a gene flow study between alfalfa seed production fields, and specifically that it is inappropriate to reach the conclusion from Hammon's study that Dr. Gurian-Sherman does here. It is

inappropriate to interpret Mr. Hammon's results as a demonstration that isolation distances will not be effective in controlling pollen movement between seed fields as experimental controls and the design of the experiment were not established to answer the question of seed production isolation distances. All the other studies on gene flow, including those offered by Dr. Tueber and by me in my second declaration, contradict Dr. Gurian-Sherman's conclusion about the single data point at issue, and support extremely low levels of AP—near zero—with the isolation distances that would be imposed under APHIS' proposed relief.

33. Perhaps most telling in Dr. Gurian-Sherman's declaration is what he does not say. For example, he does not say that there is any realistic chance of contamination from one hay field to another.

DECLARATION OF ALLISON SNOW

34. I have reviewed the declaration of Allison Snow, which Plaintiffs submitted on April 6, 2007, in support of Plaintiffs Permanent Injunction. Below, I comment on several statements in that declaration.

35. I have reviewed Dr. Snow's qualifications and experience, and her training and experience in general are applicable to the issues before the Court. Dr. Snow is a plant ecologist. Plant ecologists observe natural plant populations and environments and try to draw conclusions from their measurements. Dr. Snow has researched and published on gene movement in wild radish but it is not clear that Dr. Snow has specific experience with alfalfa.

36. Dr. Snow makes several unremarkable statements. For example, she states that stewardship "cannot completely eliminate" risk. (Snow Decl. ¶ 5.) This statement does not support Plaintiffs' allegation

that contamination will eliminate all non-GE alfalfa crops within two years. Furthermore, Dr. Snow states that containment is impossible once "unrestricted" commercial use begins. (*Id.* ¶ 6.) That is not relevant here because specific stewardship measures are proposed for seed and forage production during the period of time required for the completion of the EIS. Dr. Snow also states that bees may carry pollen for more than one mile. (*Id.*) Indeed, honeybees have a greater potential to move pollen longer distances than alkali or leafcutter bees which reinforces the importance of the three-mile isolation where honeybees are the primary pollinator in alfalfa seed production (2d Hoffman Decl. ¶ 7, Ex C.). Therefore FGI imposes a three-mile isolation when honeybees are used primary pollinator for Roundup Ready alfalfa seed production.

37. Dr. Snow states that "transgene that confers glyphosate resistance in alfalfa has already spread from cultivated fields to feral alfalfa in Fruita, CO." (Snow Decl. ¶ 6.) This has not yet been established. The Hammon study did demonstrate pollen movement to feral alfalfa from Roundup Ready alfalfa seed production fields was possible but did not provide evidence that any Roundup Ready feral alfalfa populations have been established. Hammon's data indicated that seed collected from feral alfalfa plants was between 0 and 9% positive for the Roundup Ready trait. Although genes may move in pollen and seed be produced, unless those seed can become established as plants with in the feral population there is no demonstrated harm from this pollen movement.

38. Dr. Snow does not conclude that significant contamination of non-GE alfalfa is imminent, and instead focuses on human error, random events, sub-

standard stewardship practices, and the forces of nature. (Snow Decl. ¶ 6.) The stewardship measures for Roundup Ready alfalfa proposed by the Government in this matter would address these problems. Dr. Snow does not address those stewardship measures.

39. Again, Dr. Snow does not state that there is any realistic chance of hay-to hay contamination or that widespread contamination is imminent. She focuses on the Hammon study (Snow Decl. ¶ 6), which involves seed production and pollen movement to feral populations. Dr. Snow does not work with alfalfa and it is very likely that she has limited knowledge of how alfalfa is managed for forage. She may not realize that, unlike other crops such as corn and soybeans which are grown for seed, flowering and pollen movement in alfalfa forage production is rare.

40. Finally, Dr. Snow concludes that, although transgene flow may be inevitable and that zero tolerance is impossible, "low levels of such AP is rarely a problem with nontransgenic varieties" (Snow Decl. ¶ 6), suggesting that there is no environmental harm here. Thus, she acknowledges that low levels of biotech AP are "rarely a problem" in other crops. (*Id.*)

DECLARATION OF CLINTON SHOCK

41. I have reviewed the declaration of Clinton Shock, which Plaintiffs submitted on April 6, 2007, in support of Plaintiffs Permanent Injunction. Below, I comment on several statements in that declaration.

42. Dr. Shock discuss the presence of hard seed, which, according to him, contributes to the risk of gene transmission. The hard seed Dr. Shock is concerned about is that left in the field after harvest and not in

the seed bag. Hard seed that is harvested is treated (scarified) or "scored" to take up water and it becomes less "hard" with time and germinates in the soil. Hard seed is a non-issue in hay fields rotated to other crops. The challenge in hay field rotated to corn or another crop is effectively killing the established alfalfa plant before planting the next crop. This usually requires the use of herbicides other than glyphosate (even for conventional alfalfa) and tillage. After approximately three years of seed production the alfalfa stand is killed and the field is rotated to another crop for a minimum of three years. The field may also be irrigated multiple times prior to planting the rotation crop to encourage germination of the seed that was dropped during harvest and then killed with herbicide. Herbicides would be used in the rotation crop to kill the alfalfa that would germinate as volunteers—even Roundup Ready volunteers. Growers know that they planted into a former seed field they expect volunteers and have a plan to control them before planting their rotation crop.

43. Dr. Shock also states that, because glyphosate is used to eradicate feral alfalfa, "the genetic composition of feral alfalfa will shift towards RR alfalfa." (Shock Decl. ¶ 6.) Glyphosate is not particularly effective in controlling feral or established alfalfa stands. University weed scientists recommend dicamba, 2,4-D or tank mixtures of dicamba and 2,4-D for alfalfa stand take out. (*See* Monsanto & FGI's Pet. for a Determination of Nonregulated Status for Roundup Ready Alfalfa under the Plant Protection Act, 7 U.S.C. §§ 7701 *et seq.*, Apps. 2-3.) Glyphosate may be used for roadside sprayings in tank mixtures with dicamba or 2,4-D. In these mixtures, dicamba or 2,4-D will kill alfalfa and other broadleaf weeds while

glyphosate will target the grasses. As a result of limited or no use of glyphosate alone to kill alfalfa, it is unlikely that the Roundup Ready trait will be pervasive in feral alfalfa populations.

44. In order for a plant or plant characteristic to become pervasive or spread broadly there must be a selective advantage for that plant or trait in the environment. Apart from selection by repeated applications of glyphosate only there is no selective advantage to the Roundup Ready trait in feral alfalfa.

45. As with Plaintiffs' other submissions, Dr. Shock does not state that there is any realistic chance of hay-to-hay contamination or that widespread contamination is imminent. Dr. Shock limits his discussion to seed production. Even in this scenario, Dr. Shock states that Roundup Ready traits may "eventually be passed to conventional alfalfa seed" (Shock Decl. ¶ 10) but he does not state that such movement is imminent.

DECLARATION OF JIM BRIGGS

46. I have reviewed the declaration of Jim Briggs and its attachments, which Plaintiffs submitted on April 6, 2007, in support of Plaintiffs Permanent Injunction. Below, I comment on several statements in that declaration.

47. Mr. Briggs provides a copy of a letter from Dairyland Seed Company President Steven Strachota written to Greg Lowery, Executive Vice President of the Idaho Crop Improvement Association (Briggs Decl., Ex. C) detailing detection of the Roundup Ready trait in conventional lots of seed produced by Dairyland (Briggs Decl. ¶ 14). This point is irrelevant. First, the AP for the seed lots represented in Mr. Strachota's letter are all below the maximum 1% level of AP

accepted by the Idaho Seed Improvement Association with applicable stewardship measures. (*See* Gurian-Sherman Decl., Ex. N.) Second, there is no evidence that this AP was wide spread or pervasive. The Strachota letter does not indicate the percent of the total seed lots tested that these 11 samples represent. One might surmise a major alfalfa seed company, such as Dairyland, would likely have hundreds or as many as a thousand seed lots. A total of 11 seed lots with detectable AP would suggest that a very low percentage of the Dairyland seed lots had any detectable levels of AP, but with the lack of pertinent information on the number of seed lots tested this is only a guess.

48. Mr. Briggs states that he has a seed production contract with an alfalfa seed company for conventional alfalfa seed with an established maximum of 1% AP of Roundup Ready alfalfa trait. (Briggs Decl. ¶ 4.) Mr. Briggs is incorrect in his assertion that, should he have AP of the Roundup Ready trait in a seed lot from a field above the 1% threshold of his contract, he will need to destroy the field as he will no longer be able to meet his contract for seed purity. (*Id.* ¶ 20.) If the trait in his field is due to pollen flow from a nearby Roundup Ready alfalfa field the AP observed will affect that year's seed crop only. It will not change the basic nature of the plants in his field. If the plants in his field are GE-free they will remain GE-free even if they are pollinated with pollen from a Roundup Ready alfalfa seed field. Only if the seed he received from his supplier had levels of AP approaching the 1% threshold would he need to be concerned about the percent of seed produced from his crop that might carry the Roundup Ready trait. Certainly, that seed can be

tested for AP before sale. One other item of note: none of the data presented in any of Plaintiffs' papers suggests any level of pollen contamination of a non-Roundup-Ready alfalfa seed crop beyond the 1% tolerance level in Mr. Briggs' contract.

DECLARATION OF CHARLES BENBROOK

49. I have reviewed the declaration of Charles Benbrook and its attachments, which Plaintiffs submitted on April 6, 2007, in support of Plaintiffs Permanent Injunction. Below, I comment on several statements in that declaration.

50. Although he suggests in his declaration that he has first-hand knowledge of the alfalfa industry it is clear from his comments that he has little or no understanding of alfalfa seed production. Dr. Benbrook suggests that Roundup Ready alfalfa contract seed producers could harvest their alfalfa seed fields for hay to reduce the economic loss if they could no longer harvest Roundup Ready alfalfa seed. (Benbrook Decl. ¶ 17.) Given planting rates and plant density for seed production are less than 5% of those for hay fields this would be a completely unprofitable option for the seed grower to harvest their seed fields for hay.

51. Dr. Benbrook goes on to assert that hay-to-hay transmission of the Roundup Ready trait to organic fields will jeopardize the price premium received by the organic grower. (Benbrook Decl. ¶ 29.) As the Chief Scientist for the Organic Center he should be aware that organic certification is based on the process of crop production and not on the results of crop or product testing and that if pollen flow occurred it would not negate the organic certification of the crop. But he is also missing a basic principle of premium alfalfa hay production. Alfalfa hay growers must

harvest their hay at or before the late bud to early bloom stage for best hay quality and greatest value. Therefore, receptive flowers would be rare or nonexistent in the organic field and receptive flowers are required for pollen movement. As discussed earlier in this declaration, the potential for hay-to-hay transmission of the Roundup Ready trait is an exceptionally rare event.

* * *

Weed Resistance Will Not Irreversibly Harm Farmers or The Environment

96. As I discussed above and in my previous declarations, the potential for the development of glyphosate resistant weeds in Roundup Ready alfalfa is exceedingly low, particularly over the two year period it will take for USDA to complete additional environmental review ordered by the Court.

97. Herbicide resistant weeds can be and are controlled through a variety of already existing techniques and alternative mechanisms, including tillage, mowing and the use of other herbicides. These techniques are readily available and easily used by farmers. Of course, even in the extremely unlikely event glyphosate weed resistance were to develop, there would be no harm to organic farmers because they do not use glyphosate and there would be no difference whatsoever in their weed treatment measures on organic farms.

I declare, under penalty of perjury, that the forgoing is true and correct to the best of my present knowledge.

Executed this 20th day of April 2007 in St. Louis, Missouri.

/S/

Paulette E. Pierson, Ph.D.

Attorney Signature Attestation

I, Holly J. Tate, counsel for Monsanto Company, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

/S/

Holly J. Tate

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC., and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB **REBUTTAL TESTIMONY OF MARK McCASLIN** DATE: April 27, 2007 TIME: 11:00 a.m. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. Mark H. McCaslin. My business address is P.O. Box 415, Prior Lake, Minnesota 55372.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am the cofounder and current president and research director of Forage Genetics, Inc. ("FGI"), doing business as Forage Genetics, International, a wholly owned subsidiary of

Research Seeds, Inc., which is a wholly owned subsidiary of Land O'Lakes, Inc.

Q. HAVE YOU OFFERED ANY PREVIOUS TESTIMONY IN THIS CASE?

A. Yes. I submitted a declaration on March 2, 2007, in support of FGI's motion to intervene; a declaration on March 7, 2007, in response to Plaintiffs' motion for permanent relief; a declaration on March 8, 2007, following the Court's hearing on the question of preliminary relief; and direct testimony on March 23, 2007, on the question of permanent relief. In my earlier declarations, I described my experience and qualifications.

* * *

III. RESPONSE TO PLAINTIFFS' ALLEGATIONS THAT THERE HAVE BEEN INSTANCES OF CONTAMINATION INVOLVING ROUNDUP READY ALFALFA

Q. PLAINTIFFS SUBMIT A LETTER FROM PAUL FREY, PRESIDENT OF CAL/WEST SEEDS, TO APHIS, SUGGESTING THAT CAL/WEST DISCOVERED THE ROUNDUP READY GENE IN ONE OF ITS FOUNDATION SEED LOTS. HAVE YOU READ THIS LETTER?

A. Yes. I have read Paul Frey's April 5, 2007 letter to APHIS regarding Cal/West's alleged discovery of the Roundup Ready gene in a foundation seed lot that was produced in 2003.

Q. WAS FGI RESPONSIBLE FOR THE PRESENCE OF THE ROUNDUP READY GENE THAT IS DESCRIBED IN THE LETTER?

A. No. In 2003, FGI had only one seed production field in California using Roundup Ready alfalfa. This field was the subject of an APHIS-permitted honeybee pollen flow study conducted by scientists at the University of California at Davis. This field was located on the Boswell Ranch near Corcoran, California, which is more than 200 miles south of Solano County, where the Cal/West field is located. There were no Roundup Ready alfalfa forage trials in California during the 2003 growing season. Because the Boswell Ranch was the only place in California where there was any Roundup Ready alfalfa in 2003, it is simply not plausible to claim that FGI was responsible for the presence of the Roundup Ready gene found in the Cal/West foundation seed produced in 2003.

I believe a more likely explanation is that Cal/West contaminated its own foundation seed. Cal/West had a research license from Monsanto to conduct transgenic research on Roundup Ready alfalfa from 1998 to 2002. Gene flow from Cal/West transgenic plants in a greenhouse or lab, or unintentional mixtures between transgenic and conventional seed and/or plants, is the most likely cause of the reported contamination. It is also possible that the low levels of adventitious presence (AP), ranging from 0.1% to 0.3%, were the result of a false positive test result. Third-party testing laboratories routinely test thousands of samples of Roundup Ready corn, soybeans, and cotton, and low amounts of AP can appear in test results when there is residue in the laboratory equipment.

Q. MR. FREY'S LETTER ALSO DESCRIBES AN INCIDENT IN POWELL, WYOMING, WHERE THERE WAS A ROUNDUP READY SEED PRODUCTION FIELD NEAR A SEED PRODUCTION FIELD CONTRACTED BY CAL/WEST. ARE YOU FAMILIAR WITH THAT INCIDENT?

A. Yes. On April 1, 2005, a grower under contract with FGI planted an APHIS-permitted Roundup Ready seed production field near Powell, Wyoming. Before the planting occurred, a field inspector employed by FGI confirmed by checking with the Wyoming seed certification office that there were no other alfalfa seed fields within one mile of where the Roundup Ready alfalfa seed field would be established. After the FGI grower planted its field, Cal/West planted an alfalfa seed production field less than 200 feet away. While conducting a field inspection on July 12, 2005, the FGI field inspector noticed the nearby field. He immediately contacted his supervisor at FGI, Jose Arias. I learned about the situation soon afterwards from Jose Arias, and I immediately contacted Paul Frey of Cal/West. Roundup Ready alfalfa was deregulated at that time. Paul Frey informed me that the Cal/West seed was not destined for an AP-sensitive market, and he was comfortable if the two fields remained in place near one another. We mutually agreed to leave both fields in place for the 2005 harvest. At the end of the season, FGI asked its grower to remove its field, as a precaution. According to the Wyoming seed certification office, the Cal/West field was planted on May 1, 2005, a month after the FGI field was planted.

Q. PLAINTIFFS ALSO SUBMITTED A LETTER THAT STEVEN STRACHOTA, THE PRESIDENT OF DAIRYLAND SEED COMPANY, WROTE TO GREG LOWRY OF THE IDAHO CROP IMPROVEMENT ASSOCIATION, STATING THAT DAIRYLAND FOUND THE ROUNDUP READY GENE PRESENT IN SOME OF ITS CONVENTIONAL ALFALFA SEED. ARE YOU FAMILIAR WITH THAT LETTER?

A. Yes. I have read Steven Strachota's November 1, 2006 letter to Greg Lowry. I have also talked with Tom Strachota, the CEO of Dairyland Seed, about this issue.

Q. DO YOU HAVE ANY RESPONSE TO THE TEST RESULTS CONTAINED IN THE LETTER?

A. It is widely known in the seed industry that Dairyland has established an internal adventitious presence standard for biotech traits in their non-biotech alfalfa seed. Dairyland's internal standard permits 1% AP of biotech traits in its seed. This standard is contained in Dairyland's contracts with its seed growers. The test results in Steven Strachota's letter state that the levels of AP that Dairyland found in its seed ranged from trace amounts (less than 0.1%) to 0.9%. I was pleased to learn that the levels of AP were very low, and that none of the AP levels exceeded Dairyland's internal standard. This demonstrates that stewardship mandated isolation distances, and communication between seed companies, have been successful.

Q. STEVEN STRACHOTA'S LETTER STATES THAT AP WAS FOUND IN ELEVEN DAIRYLAND LOTS. THE PLAINTIFFS ALSO SUBMIT A DECLARATION FROM JIM BRIGGS, WHO STATES THAT HE OVERHEARD A

DAIRYLAND EMPLOYEE STATE THAT SIXTEEN LOTS OF NON-ROUNDUP READY ALFALFA HAD TESTED POSITIVE FOR THE ROUNDUP READY GENE. DO YOU HAVE ANY RESPONSE?

A. Dairyland Seed is one of the three largest alfalfa seed producers in the United States. A company the size of Dairyland is likely to harvest *at least* several hundred seed lots each year. (In comparison, FGI harvests more than 1,000 seed lots each year.) I understand that between eleven and sixteen of Dairyland's lots had very low amounts of AP. This is not surprising, given the total number of lots a large seed company produces. FGI conducts random samples of its own conventional seed lots, and we have found that a very low percent of our seed lots have any detectable levels of the Roundup gene. FGI routinely tests seeds that it sells to organic and GE-sensitive alfalfa hay growers. I believe that FGI is currently the largest seller to such growers, and FGI has no trouble producing and selling seed without any detectible trace of the Roundup gene.

Q. ARE YOU AWARE OF ANY OTHER INSTANCES OF CONTAMINATION OF NON-ROUNDUP READY ALFALFA SEED OR HAY?

A. No. We have not received any other reports of AP of the Roundup Ready gene, either from seed growers or hay growers. We have never received reports of AP from any organic grower. Out of approximately 130,000 alfalfa seed production acres in the country, Plaintiffs have only pointed to a few isolated instances of AP. Out of more than 22 million hay production acres, Plaintiffs

have not pointed to a single instance of contamination.

Q. DO DAIRYLAND OR CAL/WEST PRODUCE OR SELL ROUNDUP READY ALFALFA SEED?

A. Both Dairyland and Cal/West sell Roundup Ready alfalfa seed, although neither company currently produces Roundup Ready seed. Dairyland and Cal/West are both customers and competitors of FGI.

* * *

V. RESPONSE TO PLAINTIFFS' ARGUMENT THAT THE SPREAD OF THE ROUNDUP READY TRAIT WILL BE IRREVERSIBLE ONCE IT OCCURS

Q. PLAINTIFFS SUBMIT STATEMENTS FROM SEED AND HAY GROWERS WHO SUGGEST THAT ONCE CONTAMINATION OCCURS, IT WILL BE IRREVERSIBLE. FOR INSTANCE, JOHN MARKEGARD AND LARRY MEYER STATE THAT IF THEIR CONVENTIONAL SEED FIELDS BECOME CONTAMINATED, THEY COULD BE CONTAMINATED FOR YEARS. ARE THESE FEARS WELL-FOUNDED?

A. No. The only practical mechanism for gene flow into a seed production field is through pollen movement. A pollen grain carried by a bee pollinator from a neighboring field contributes half of the genes contained in a single developing seed. Once the seed is harvested, the genetic "contribution" is removed. The genetic makeup of the plants in the seed production stand is unchanged. Any seeds remaining in the field are removed using routine weed and volunteer control practices, leaving no mechanism for permanent

contamination of a seed production field from incoming pollen.

Q. PLAINTIFFS SUBMIT STATEMENTS THAT SUGGEST WIDESPREAD CONTAMINATION OF ALFALFA SEEDSTOCKS IS LIKELY AND THAT THIS CONTAMINATION WOULD BE IRREVERSIBLE. ARE THESE FEARS WELL-FOUNDED?

A. No. The standard practices for the production and preservation of alfalfa breeder seedstocks are specifically designed to ensure the highest levels of genetic purity. Precise characterization of parent plants/lines and extraordinary procedures for managing pollen flow in breeder seed production are critical quality control measures in any plant breeding program. When low levels of "off type" contamination are identified, there are very simple and effective processes for removing these unwanted genetic traits from plant populations and "cleaning up" potential contamination. The process consists of planting out a small population of plants from a potentially contaminated breeder seed lot, eliminating any plants containing the unwanted gene or trait, and intercrossing the remaining non-contaminated plants. This process takes a single growing season. These procedures are widely and routinely practiced by plant breeders to ensure that plant varieties remain "true to type" and do not contain genes or traits (biotech or conventional) that are undesirable. In plant breeding programs, occasional "off types" in breeding populations and seedstocks are infrequent, and identifying and eliminating these "off types" is part of a standard quality control

program. Virtually all plant breeding companies have controlled storage facilities that are used for long-term storage of critical breeding lines and seedstocks.

Q. DOES HARD SEED CONTRIBUTE TO THE POSSIBILITY THAT CONTAMINATION WILL BE IRREVERSIBLE?

A. No. As I discussed in my second declaration on March 7, 2007, research data on hard seed shows that the vast majority of hard seed germinates in the first couple of weeks after planting. See Dan Undersander et al., Hard Seed in Alfalfa (2001), available at http://www.uwex.edu/ces/forage/pubs/hardsd.htm. This data is based on a multi-year, multi-location study. A two-year rotation requirement (i.e. a two year prohibition on planting new alfalfa production after termination of an existing stand) for certified alfalfa seed production adds further insurance that hard seed and/or volunteers will not contaminate succeeding alfalfa seed crops.

Q. HAVE YOU TAKEN INTO ACCOUNT WHETHER FERAL BEES ARE LIKELY TO CONTRIBUTE TO THE POSSIBILITY OF CONTAMINATION?

A. Yes. The pollen flow studies that are the basis for current isolation requirements take into account the feral bee population, since any feral bees present in the environment were also present during the studies. The feral bee population has been factored into the current isolation distances.

Q. PLAINTIFFS SUBMITTED DECLARATIONS FROM DAVID LEE MCSHERRY AND GARY ZIMMER, WHO EXPRESSED CONCERN ABOUT THE PURITY OF THE SEED VARIETIES THEY PURCHASE FOR THEIR HAY

OPERATIONS. HOW CAN ORGANIC AND OTHER HAY GROWERS WHO WISH TO GROW NON-ROUNDUP READY HAY PROTECT THEMSELVES?

A. The most important step a hay grower can take to protect against the adventitious presence of the Roundup Ready gene in hay is to purchase non-GE seed. Because of extraordinary insect pressure (e.g., from the Lygus bug) on alfalfa seed production in the United States, there is virtually no organic alfalfa seed production in the country. FGI has diligently tried, without success, to identify organic alfalfa seed producers in the United States for our organic hay producer customers. Most organic hay producers in the United States plant seed of a modern non-biotech multiple pest resistant alfalfa variety, a practice which is permitted by the National Organic Program. I believe FGI is currently the largest supplier of this seed to organic hay producers in the United States. We routinely test for AP on seed destined for the organic hay market, and have not had any trouble providing non-GE seed to organic and AP-sensitive conventional hay growers since APHIS deregulated Roundup Ready alfalfa. In addition, one of FGI's largest seed company customers will offer "certified non-GE" alfalfa seed for grower purchase in 2008. The production of non-Roundup Ready seed varieties currently comprises approximately two-thirds of FGI's business, and to my knowledge, no alfalfa seed grower or seed seller has reported a loss of any market due to levels of AP in conventional alfalfa seed.

Q. WOULD LOW LEVELS OF ADVENTITIOUS PRESENCE IN ORGANIC HAY JEOPARDIZE MARKETS FOR NON-GE ORGANIC MILK OR MEAT?

A. No. First of all, I believe that it will always be possible for organic hay producers to purchase non-GE seed and produce non-GE hay. Our company, and probably many others, are committed to serving this seed market. In the unlikely event that there are low levels of Roundup Ready AP in organic hay, there will be no detectable biotech product in the milk or meat produced from animals that are fed this hay. Animal research studies document that even when livestock are fed GE feed, the resulting milk and meat products contain no trace of GE products. See http://anrcatalog.ucdavis.edu/pdf/8183.pdf. All ingested plant proteins are either digested or bypassed, and there is no direct incorporation into animal products.

Q. IS THERE A DANGER OF ROUNDUP READY ALFALFA PROLIFERATING IN THE GENERAL POPULATION OF FERAL PLANTS IN THE LANDSCAPE?

A. No. In the absence of glyphosate herbicide application, there is no selective advantage of Roundup Ready alfalfa versus conventional alfalfa as feral plants in the landscape. Glyphosate is very seldom used to control feral alfalfa plants. Feral alfalfa plants are generally not considered to be a weed, and are often harvested on roadsides as a source of low-cost forage.

Q. WHAT REQUIREMENTS DO ORGANIC FARMERS ADHERE TO UNDER THE NATIONAL ORGANIC

PROGRAM TO ENSURE THAT THEIR FARMS REMAIN ORGANIC?

A. In order to become a certified organic operation, organic farmers must submit an organic system plan to a USDA-accredited certifying agent. The plan must demonstrate that the organic grower will comply with the requirements of the National Organic Program. These requirements include defined boundaries for fields, buffer zones to ensure the integrity of the organic crop operation, preventive practices to manage pests, weeds and diseases, and use of appropriate seeds. See NOP Regulations, 7 C.F.R. § 205. NOP guidance states that in the event that all precautions have been taken, and an approved buffer zone fails to provide the protection that both the operator and the certifying agent reasonably expected, certifying agents may not retroactively punish the producer by an enforcement action or decertification. Instead, the certifying agent and the producer are instructed to re-evaluate the buffer zone and other preventive measures to ensure improved integrity and performance in the future. See USDA NOP website, "Questions and Answers," available at http://www.ams.usda.gov/NOP/Q&A.html-Production/Handling.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 20th day of April 2007 at Minneapolis, Minnesota.

/s/
MARK McCASLIN

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/
B. ANDREW BROWN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE CHARLES R. BREYER

GEERTSON SEED FARMS, ET AL,	)	
PLAINTIFFS,	)	
VS.	)	NO. C-06-1075 CRB
MIKE JOHANNS, SECRETARY OF THE UNITED STATES DEPARTMENT OF AGRICULTURE, ET AL.,	)	SAN FRANCISCO, CALIFORNIA FRIDAY,
DEFENDANTS.	)	APRIL 27, 2007

TRANSCRIPT OF PROCEEDINGS

* * *

[13] . . . Have stepped up, and there would have been more environmental impacts here.

Very similarly, in our case, there are some significant environmental and societal benefits to allowing the use of roundup ready alfalfa those include.

THE COURT: You can't argue your result. See, the problem is—yes, I'm not saying, and I haven't said, that roundup ready alfalfa might be the greatest thing since penicillin. I don't know. I don't think it is, and I

don't think you are claiming that. I don't know. I don't know.

And then I fault to the government again for not knowing its beneficial effects, but not studying the environmental impact it could have. That's what I faulted the government with having done.

So I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it, you know, and all the measures and so forth. We allow the government in the first instance to do that.

It just seems to me that everything that you've presented to me, with due respect, essentially is the argument that I could be like a super environmental agency engaged in balancing all of these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And, number two, it isn't my job. It didn't **[14]** come with my job description. It came with the job description of the government of the United States. Congress told the government to do this, the executive branch to do it, not the judicial branch.

And so your arguments, for the most part, as I have interpreted them have really—at its base level have suggested to me that I ought to be engaged in this process that I'm perfectly capable of doing. I don't know whether I am or not, but having found that it ought to be the government that does it, I thought my case is very simple what I should do.

I should make sure that the harm, if there is harm, doesn't increase. I should stop things in its place until the Government has discharged its duty given to it by the right of Congress of the United States.

Once that's done, then whatever those conclusions are and whatever the basis is, then it's out there. It's been studied, and it's been released.

And but—but for you to come in, and I mean this deferentially, because i mean I don't—I'm not accusing you—I'm saying for a party to come in and say, well, look, judge, we think that you ought to increase the use of this product pending the determination because we're sure it's safe, and, by the way, we're sure that—not just safe, we're sure that it won't result in the destruction of biodiversity, that we are sure that it can be controlled in a way that it won't . . .

* * *

OPPOSITION BRIEF

No. 09-475

In the Supreme Court of the United States

MONSANTO COMPANY, ET AL., PETITIONERS

v.

GEERTSON SEED FARMS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

This case arose out of the decision of the Animal and Plant Health Inspection Service (APHIS) to deregulate alfalfa that had been genetically engineered to tolerate glyphosate, the active ingredient in the herbicide Roundup, based on APHIS's determination that the alfalfa did not present a plant pest risk. After finding that APHIS had not adequately analyzed the environmental impacts of its deregulation action under the National Environmental Policy Act, 42 U.S.C. 4321 *et seq.*, the district court entered, and the Ninth Circuit affirmed, a permanent injunction requiring APHIS to prohibit further planting of Roundup Ready alfalfa pending the agency's completion of an Environmental Impact Statement and final decision regarding deregulation. The questions presented are:

1. Whether the Ninth Circuit erred in affirming the permanent injunction entered by the district court, where the district court applied an incorrect legal standard that presumed irreparable harm.

2. Whether the Ninth Circuit erred in determining that the district court did not abuse its discretion when it declined to hold an evidentiary hearing before it entered the permanent injunction.

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OPINIONS BELOW

The amended opinion of the court of appeals (Pet. App. 1a-26a) is reported at 570 F.3d 1130. The opinion of the district court (Pet. App. 60a-79a) is unreported.

JURISDICTION

The amended judgment of the court of appeals was entered and a petition for rehearing was denied on June 24, 2009 (Pet. App. 104a-107a). On September 17, 2009, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including October 22, 2009, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Plant Protection Act (PPA), 7 U.S.C. 7701 *et seq.*, provides that "no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit" and is in accordance with regulations issued by the Secretary of Agriculture to prevent the "introduction of plant pests into the United States or the dissemination of plant pests within the United States." 7 U.S.C. 7711(a). The Secretary of Agriculture delegated his responsibilities under the PPA to the Animal and Plant Health Inspection Service (APHIS). 7 C.F.R. 2.22(a), 2.80(a)(36). The United States Department of Agriculture (USDA) has promulgated regulations governing, *inter alia*, the introduction (*i.e.*, importation, interstate movement, or release into the environment, see 7 C.F.R. 340.1) of "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," 7 C.F.R. 340.0(a)(2) n.1. See 7 C.F.R. Pt. 340. Such items are referred to in the regulations as "regulated articles." 7 C.F.R. 340.1.

The PPA and its implementing regulations authorize any person to petition APHIS for a determination that an article does not present a plant pest risk and therefore should not be regulated under 7 C.F.R. Part 340. 7 U.S.C. 7711(c)(2); 7 C.F.R. 340.6(a). If APHIS determines, "based upon available information," that the regulated article should not be regulated under Part 340, it will approve the petition, either in whole or in part. 7 C.F.R. 340.6(d)(3). The PPA mandates that the Secretary's ultimate decision to approve or deny the petition must be based on "sound science." 7 U.S.C. 7701(4).

The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, requires that, whenever a federal agency proposes a "major Federal action[] significantly affecting the quality of the human environment," the agency must examine the reasonably foreseeable environmental effects of the proposed action and inform the public about its effects on the environment. 42 U.S.C. 4332(2)(C); 40 C.F.R. Pt. 1508; see *Baltimore Gas & Elec. Co.* v. *NRDC*, 462 U.S. 87, 97 (1983). In so doing, the agency must prepare a "detailed statement" of the environmental impact of the proposed action—an "environmental impact statement" (EIS)—the requirements of which are set out in the regulations implementing NEPA. 42 U.S.C. 4332(2)(C); 40 C.F.R. Pts. 1502, 1508. Those regulations govern, *inter alia*, an agency's decision whether to prepare an EIS for a particular project. The regulations permit an agency to comply with NEPA by preparing an "environmental assessment" (EA) in lieu of an EIS in certain circumstances. 40 C.F.R. 1501.4. The regulations define an EA as a "concise public document" that briefly describes the need for, alternatives to, and environmental impacts of the proposed federal action. 40 C.F.R. 1508.9. If the agency determines based on the EA that the proposed federal action will not significantly affect the quality of the human environment, it then makes a "finding of no significant impact" (FONSI), 40 C.F.R. 1508.13, and it need not prepare an EIS, 40 C.F.R. 1501.3. If the agency determines that the proposed action will significantly affect the environment, it must prepare a more thorough EIS. See 40 C.F.R. Pt. 1502.

NEPA "does not mandate particular results, but simply prescribes the necessary process." *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350

(1989). NEPA's "mandate to the agencies is essentially procedural" and is designed "[t]o insure a fully informed and well-considered decision" on the part of the federal agency. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978).

2. This case concerns "Roundup Ready alfalfa" (RRA), an alfalfa crop that was genetically engineered by petitioner Monsanto Company (Monsanto) to tolerate glyphosate, the active ingredient in the herbicide Roundup. Pet. App. 5a. The advantage of this tolerance to growers and seed producers of alfalfa is twofold: (1) it allows them to supply a market demand for weed-free alfalfa; and (2) it allows them to apply herbicide more sparingly because they can apply it after weeds have germinated. See *id.* at 6a. Monsanto owns the intellectual property rights to RRA and licenses the technology exclusively to co-petitioner Forage Genetics International, LLC (FGI). *Id.* at 5a.

APHIS initially classified RRA as a regulated article under the PPA. Pet. App. 5a. In 2004, petitioners submitted to APHIS a petition requesting non-regulated status for RRA under the PPA. *Ibid.* On November 24, 2004, after completing a draft EA, APHIS published a notice in the *Federal Register* (1) advising the public of APHIS's receipt of the petition, (2) making the EA available for public comment, and (3) soliciting public comment on whether RRA presents a plant pest risk. See *id.* at 6a; 69 Fed. Reg. 68,300-68,301.

On June 27, 2005, APHIS published in the *Federal Register* a notice that it had prepared a final EA regarding the possibility of deregulating RRA and had "reached a finding of no significant impact." 70 Fed. Reg. 36,917-36,919. APHIS issued the FONSI after analyzing "data submitted by Monsanto/FGI, a review

of other scientific data, field tests of the subject alfalfa, and comments submitted by the public." *Id.* at 36,918. Based on that analysis, APHIS determined that RRA: (1) exhibits no plant pathogenic properties; (2) exhibits no characteristics that would cause it to be more weedy than other alfalfa; (3) is unlikely to increase the weediness potential of other species; (4) will not damage raw or processed agricultural commodities; (5) should not damage or harm organisms beneficial to agriculture; and (6) should not reduce the ability to control pests or weeds in alfalfa or other crops. *Id.* at 36,918-36,919. On the basis of its FONSI, APHIS concluded that it did not need to prepare an EIS, and it unconditionally deregulated RRA. Pet. App. 7a.

3. a. In February 2006, more than eight months after APHIS's decision to deregulate RRA, respondents Geertson Seed Farms and others (plaintiffs) filed suit against the Secretary of Agriculture and other federal officials alleging violations of NEPA, the Endangered Species Act (ESA), and the PPA. Pet. App. 7a, 27a. Because plaintiffs did not seek preliminary injunctive relief prior to a determination of the merits of their claims, RRA was commercially planted pursuant to its deregulated status beginning June 14, 2005. *Id.* at 55a, 58a. On cross-motions for summary judgment, the district court found that APHIS had violated NEPA in failing to prepare an EIS. *Id.* at 37a-53a. The court noted that it was called upon to answer what it identified as a "close question of first impression: whether the introduction of a genetically engineered crop that might significantly decrease the availability or even eliminate all non-genetically engineered varieties is a 'significant environmental impact' requiring the preparation of an environmental impact statement." *Id.* at 27a. The court

ultimately found that APHIS's EA was insufficient in two respects: (1) it did not adequately consider the potential for gene transmission between RRA and non-genetically engineered alfalfa; and (2) it did not adequately consider the potential for the development of glyphosate-resistant weeds. *Id.* at 7a-8a, 32a-51a. The district court declined to reach the respondents' ESA and PPA claims. *Id.* at 51a.

Following the district court's decision on the merits, petitioners moved to intervene as defendants for the remedial phase of the litigation. The district court granted their motions, agreeing to give them the opportunity "to present evidence to assist the court in fashioning the appropriate scope of whatever relief is granted." Pet. App. 54a (citing *Forest Conservation Council* v. *USFS*, 66 F.3d 1489, 1496 (9th Cir. 1995)); *id.* at 8a. The court received evidence from all parties and heard several hours of oral argument, on the basis of which it issued a preliminary injunction. *Id.* at 63a; see *id.* at 54a-59a. APHIS proposed a remedy under which it would, in addition to preparing an EIS, impose six restrictions on the planting of RRA and on the handling of RRA seed pending the completion of the EIS. *Id.* at 184a-187a. Instead of adopting APHIS's suggested limitations, however, the district court issued a preliminary injunction on March 12, 2007, enjoining all planting of RRA and all sales of RRA seed beginning March 30, 2007. *Id.* at 8a, 54a-59a.

The district court cited *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), for the proposition that, "[i]n the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured." Pet. App. 55a. But the court noted that

this was not a run of the mill case in certain respects because some alfalfa growers had already purchased and planted RRA in reliance on APHIS's deregulation decision. *Id.* at 8a, 55a. The district court did not require those growers to remove or destroy their already-planted RRA; the court also allowed growers who had already purchased RRA seed to plant it until March 30, 2007. *Id.* at 8a, 55a-58a. In other respects, however, the court found that this case was a "run of the mill" NEPA case, and that neither APHIS nor petitioners had identified any "unusual circumstances" that would lead the court to permit an increase in the number of acres planted with RRA while the court considered the appropriate scope of permanent injunctive relief. *Id.* at 56a-57a. The court noted that it would consider "whatever additional evidence [petitioners] wish to provide," would provide APHIS the opportunity to present additional evidence, and would allow plaintiffs to respond to any such evidence before fashioning permanent injunctive relief. *Id.* at 58a-59a.

The parties submitted evidence concerning the appropriate scope of permanent injunctive relief, Pet. App. 9a, 64a, and the court issued such relief on May 3, 2007, *id.* at 60a-79a. The court ordered APHIS to prepare an EIS and enjoined all planting of RRA from March 30, 2007, until the completion of the EIS. *Id.* at 79a. In its order, the court acknowledged that petitioners had "requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." *Id.* at 67a. The court rejected that request based on its view that making the findings requested by petitioners would be tantamount to "en-

gag[ing] in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." *Id.* at 68a.

The district court explained that it rejected APHIS's proposed restrictions on the planting and harvesting of RRA because APHIS had not submitted evidence suggesting that its proposed interim conditions would be followed. Pet. App. 69a-70a. In addition, the court criticized the efficacy of particular proposed restrictions in eliminating the possibility of gene flow because growers cannot always harvest at the optimal time due to weather restrictions. *Id.* at 70a-71a. The court also found that "contamination of organic and conventional alfalfa crops with the genetically engineered gene has occurred and defendants acknowledge as much. Such contamination is irreparable environmental harm." *Id.* at 71a; see *id.* at 70a-71a. The court concluded that the harm to "farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa." *Id.* at 71a.

b. APHIS and petitioners appealed on the ground that the permanent injunction was overly broad. Pet. App. 10a. Petitioners further argued that the district court erred by denying their request for an evidentiary hearing. *Id.* at 16a. No appellant challenged the district court's merits determination that APHIS's NEPA analysis was insufficient. *Id.* at 5a. On June 24, 2009, the court of appeals issued an amended decision affirming the district court's entry of the permanent injunction. *Id.* at 1a-20a.

The court of appeals found that "the record demonstrates that the district court applied the traditional four-factor test" for the issuance of an injunction, as

"required by" *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006). Pet. App. 13a; *id.* at 10a-16a. The court noted that the district court had found that gene contamination of organic and conventional alfalfa had already occurred while petitioners had contractual obligations in place that were similar to the proposed mitigation measures, and that such contamination constituted irreparable harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. *Id.* at 13a-14a. The court also found that the district court adequately considered the interests of both petitioners and the public. *Id.* at 14a-15a. In upholding the scope of the injunction, the court of appeals rejected the government's argument that the district court should have deferred to the agency's proposed interim measures. *Id.* at 15a-16a.

Finally, the court rejected petitioners' argument that the district court erred in declining to hold an evidentiary hearing before issuing the permanent injunction. Pet. App.16a-20a. The court reasoned that, although a district court should generally hold an evidentiary hearing absent waiver by the adverse party, the district court in this case "did not believe defendants had established any material issues of fact that were in dispute in the case before the court." *Id.* at 17a. The court of appeals also noted that the injunction at issue here was similar to the one at issue in *Idaho Watersheds*—where the court of appeals also upheld a permanent injunction issued without the benefit of an evidentiary hearing, 307 F.3d at 830-831—because the injunction will be in effect only until APHIS completes an EIS. Pet. App. 17a-19a. In addition, the court disagreed with the dissent on the antecedent issue of whether the district court failed to

hold an evidentiary hearing at all, noting that the court held one hearing on the NEPA violation, held two hearings on the scope of injunctive relief, and reviewed extensive documentary submissions. *Id.* at 19a-20a.

Judge Smith dissented on the issue of whether the district court should have held an evidentiary hearing before issuing the permanent injunction. Pet. App. 20a-26a. He would have held that, under Federal Rule of Civil Procedure 65, a district court must hold an evidentiary hearing unless the material facts are undisputed or the adverse party waives its right to such a hearing. Pet. App. 20a-21a (citing *Charlton* v. *Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). Judge Smith found that neither exception applied, and dismissed as insignificant the fact that APHIS did not request an evidentiary hearing because, he noted, petitioners did. *Id.* at 21a-22a.

ARGUMENT

The court of appeals erred in determining that the permanent injunction entered by the district court was appropriately tailored and that the district court applied the correct legal standard. Further review is not warranted, however, because the court of appeals itself set forth the correct legal standard and its decision does not squarely conflict with any decision of this Court or of any other court of appeals.

1. Neither the breadth of the injunction entered by the district court nor the propriety of the district court's approach in entering the injunction merits further review by this Court in light of APHIS's subsequent administrative action. By its terms, the injunction will terminate when APHIS completes the EIS the district court found it was required by NEPA to prepare before

deregulating RRA. See Pet. App. 79a. On December 14, 2009, APHIS announced the availability for public review of a nearly 200-page draft EIS, which addresses, *inter alia*, the potential for gene flow to conventional and organic alfalfa as well as the potential for an increase in glyphosate-resistant weeds. Http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf (draft EIS); Http://www.aphis.usda.gov/newsroom/content/2009/12/printable/alfalfa_brs.pdf (press release). The 60-day comment period (which commenced on December 18, 2009, the date of publication of the draft EIS in the *Federal Register*) will close on February 16, 2010. After the close of the public comment period, APHIS will issue a final EIS in light of its consideration of the comments it receives. Http://www.aphis.usda.gov/publications/bio-echnology/content/printable_version/faq_alfalfa.pdf (questions and answers about EIS process). When that process is complete, the injunction will expire and render the current appeal moot.

2. The government agrees with petitioners that the court of appeals erred in concluding that the district court applied the four-factor test governing the issuance of a permanent injunction. The government also agrees with petitioners that the court of appeals was wrong in finding that the district court did not presume irreparable harm from the fact of APHIS's NEPA violation. In *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006), this Court reaffirmed that:

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies

> available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. at 391. Contrary to this mandate, the district court enjoined—first preliminarily and then permanently—all commercial planting of RRA without requiring plaintiffs to demonstrate that the balance of harms necessitated such relief. Pet. App. 54a-59a, 60a-79a. Rather, the district court turned the appropriate analysis on its head by assuming that, in the "run of the mill NEPA case," an injunction is warranted halting the activity in question "until the NEPA violation is cured." *Id.* at 55a (quoting *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002)). The court thus required APHIS and petitioners to demonstrate that an injunction was not warranted due to the presence of "unusual circumstances." *Id.* at 55a-56a.[1] The district court erred in effectively applying a presumption in favor of a nationwide injunction.

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[1] Notably, the agency action at issue in this case is unlike the site-specific projects at issue in many NEPA cases, *e.g.*, timber sales or permit issuances. While a presumption of irreparable harm is no more permissible in the site-specific context than it is here, the district court's characterization of this case as a "run of the mill" NEPA case led it to enter an injunction that is significantly different from and broader than the injunctions entered in many NEPA cases. Here, the district court's injunction did not merely delay a site-specific project. Instead, it effectively required APHIS to re-regulate RRA nationwide, notwithstanding APHIS's determination that RRA did not pose a plant pest risk and should no longer be regulated under the PPA.

Although the government disagrees with the court of appeals' conclusion that the district court applied the correct legal standard, further review of that conclusion is not warranted because the court of appeals itself set forth the correct legal standard and made clear that it applies in NEPA cases. Pet. App. 12a ("The Supreme Court held in *eBay* that courts cannot grant or deny injunctive relief categorically in place of applying the four-factor test."). The court of appeals also correctly noted that NEPA plaintiffs seeking injunctive relief must demonstrate a likelihood, rather than a mere possibility, of irreparable harm in order to justify injunctive relief. *Id.* at 13a (citing *Winter* v. *NRDC*, 129 S. Ct. 365, 375 (2008)); see also *id.* at 12a (citing *Amoco Prod. Co.* v. *Village of Gambell*, 480 U.S. 531, 545 (1987)). The court of appeals' statements regarding the governing law are consistent with this Court's precedents. Although the court of appeals also noted its prior precedent stating that an injunction should issue to remedy a NEPA violation absent "unusual circumstances," *id.* at 12a, the court's acknowledgment of that precedent alone does not warrant this Court's review at the present time. This Court's decisions in *eBay* and *Winter* are relatively recent, and it would be appropriate for this Court to stay its hand in order to consider the manner in which the Ninth Circuit (and the district courts therein) will apply the principles set forth in those decisions. Thus, in spite of the fact that the government agrees with petitioners that the Ninth Circuit erred in its application of the governing legal standards to the circumstances of this case, in the government's view, this case does not appear to meet this Court's traditional criteria for plenary review.

3. There is similarly no need for this Court to review the court of appeals' determination that the district

court did not abuse its discretion by declining to hold an evidentiary hearing prior to issuing a permanent injunction. The government did not request an evidentiary hearing at that stage of the proceedings and does not believe that one was necessary in this case, although it does believe that the district court should have deferred to the remedial order proposed by the government.

The court of appeals correctly noted that, "generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed." Pet. App. 17a (citing *United States* v. *Microsoft Corp.*, 253 F.3d 34, 101-103 (D.C. Cir.), cert. denied, 534 U.S. 952 (2001); *Charlton* v. *Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). Although petitioners argue (Pet. 26-27) that the court of appeals' decision conflicts with decisions of other courts of appeals as to the necessity of holding such a hearing, the various courts in fact agree about that general rule. See *Four Seasons Hotels & Resorts, B.V.* v. *Consorcio Barr, S.A.*, 320 F.3d 1205, 1211 (11th Cir. 2003); *In re Rationis Enters.*, 261 F.3d 264, 269 (2d Cir. 2001); *Microsoft*, 253 F.3d at 101-103; *Professional Plan Examiners of N.J., Inc.* v. *Lefante*, 750 F.2d 282, 288 (3d Cir. 1984).[2] Accordingly, review is

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[2] Petitioners also argue (Pet. 21) that the court of appeals' decision conflicts with the Second Circuit's decision in *Town of Huntington* v. *Marsh*, 884 F.2d 648 (1989), cert. denied, 494 U.S. 1004 (1990), because, by refusing to require the district court to convene an evidentiary hearing, the court of appeals sanctioned the district court's assumption that the NEPA violation on its own constituted irreparable harm. That is simply another way of asserting that the district court erroneously assumed such harm. As discussed above (see pp. 11-15, *supra*), to the extent the district court assumed irreparable harm, it was in error; but because the court of appeals did not make the same error, further review is not warranted.

not required to ensure that the Ninth Circuit adopts the correct general legal principle.

Nor is there any reason for this Court to review the court of appeals' fact-specific determination that the district court did not abuse its discretion in declining to hold an hearing in this case, including its partial reliance on the fact that the permanent injunction at issue in this case would terminate as soon as APHIS cured the NEPA violation by completing an EIS. The court of appeals concluded that "[t]he district court did not believe defendants had established any material issues of fact that were in dispute in the case before the court." Pet. App. 17a; cf. *id.* at 13a (noting that the district court "found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while [petitioners] had contractual obligations in place that were similar to their proposed mitigation measures"). Although petitioners protest (Pet. 18) that there were material issue of fact in dispute, review of that issue does not merit further review because the views of the various parties as to the many issues related to the propriety of injunctive relief were fully aired before the district court. As the court of appeals noted, before the district court entered the permanent injunction, the court "considered extensive evidentiary submissions from all parties pertaining specifically to the remedy phase," Pet. App. 19a; see *id.* at 9a, and "held one hearing on the nature of the NEPA violation [and] two hearings on the scope of injunctive relief," *id.* at 19a-20a. The court of appeals thus concluded that the district court did not abuse its discretion in declining to hold a hearing specifically devoted to the issuance of a permanent injunction. *Id.* at 20a.

In addition, the granting of injunctive relief in a suit challenging agency action under the Administrative Procedure Act (APA) presents different considerations than the granting of such relief in private litigation. In an APA suit, review of the merits is based on the administrative record and is deferential insofar as factual issues are concerned. At least some factors bearing on the propriety of injunctive relief will often have already been addressed by the agency or will be on remand, and the agency should typically be given the opportunity in the first instance to address the appropriate interim response to the court's determination that the agency's prior decision was inconsistent with legal requirements. These additional considerations, which are not discussed at any length by petitioners, would have to be taken into account in a case such as this. Review should be denied for this and the other reasons discussed above, and because the injunction entered by the district court will soon expire once APHIS issues the EIS that it has already released in draft form for public comment.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 2009

OPPOSITION BRIEF

Supreme Court, U.S.
FILED
DEC 23 2009
OFFICE OF THE CLERK

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF IN OPPOSITION OF RESPONDENTS GEERTSON SEED FARMS, ET AL.

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QUESTIONS PRESENTED

For reasons set forth in the body of this brief in opposition, none of the three questions framed by the petitioners is properly presented in this case. The issues actually presented by the petition for certiorari are:

1. Whether the court of appeals correctly applied the substantive and procedural standards for granting a permanent injunction to the particular facts of this case when it affirmed the district court's issuance of a permanent injunction to remedy the undisputed violation of the National Environmental Policy Act ("NEPA") at issue in the case.

2. Whether the court of appeals correctly held that respondents had made a sufficient showing of likelihood of irreparable injury to justify the scope of the injunction.

3. Whether the court of appeals correctly held that an evidentiary hearing was unnecessary because the facts petitioners purported to dispute were not material to the proper scope of the injunction.

PARTIES TO THE PROCEEDINGS

Because the petition for certiorari omits the complete listing of the parties to the proceedings in the court below required by Rule 14.1(b), respondents supplement the statement in the petition as follows:

(1) The plaintiffs/appellees in the court below, who are respondents here, were the Center for Food Safety, Beyond Pesticides, the Cornucopia Institute, the Dakota Resource Council, Geertson Seed Farms (now known as Geertson Farms, Inc.), the National Family Farm Coalition, the Sierra Club, and the Western Organization of Resource Councils.

(2) In addition to the petitioners, the other defendants/appellants in the court below (who are respondents in this Court) were Mike Johanns, in his official capacity as Secretary of Agriculture; Steve Johnson, in his official capacity as Administrator of the U.S. Environmental Protection Agency; and Ron Dehaven, in his official capacity as Administrator of the Animal Plant Health and Inspection Service (APHIS) of the U.S. Department of Agriculture. Those officials have now been replaced as parties by their successors in office, Secretary of Agriculture Thomas Vilsack, EPA Administrator Lisa Jackson, and APHIS Administrator Cindy Smith.

RULE 29.6 STATEMENT

Respondents Center for Food Safety, Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, and Western Organization of Resource Councils are nonprofit corporations. They have no parent

or subsidiary corporations, and no stock that is owned by any other corporations.

Respondent Geertson Seed Farms was incorporated on August 16, 2007, as Geertson Farms, Inc. It has no parent or subsidiary corporations, and no other corporation owns any of its stock.

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INTRODUCTION

In this case, the court of appeals applied conventional equitable standards to affirm the district court's issuance of an injunction to remedy the government's violation of the National Environmental Policy Act (NEPA) in failing to prepare an Environmental Impact Statement (EIS) before permitting unrestricted use of genetically engineered (GE) alfalfa—a violation that is not disputed in this Court and was not disputed in the court of appeals. Indeed, the propriety of issuing some form of injunctive relief to remedy that violation was not even contested below; the only issue was its proper scope. On that question, the principal defendants—the federal officials whose actions are at issue—have *not* sought review in this Court and will soon have carried out the steps the injunction requires, upon which it will expire by its own terms.

The district court's injunction, which has now been in place for more than two-and-a-half years, prohibits the planting of GE alfalfa only until the government has completed an EIS and the Department of Agriculture has issued a new decision on whether to deregulate GE alfalfa based on the EIS. The draft EIS is now published, and the agency will very likely have finalized it and issued a new decision on deregulation of GE alfalfa before this Court would be able to hear and decide the case. Those developments would moot the issue of the propriety of the injunction. Moreover, even if the case does not become moot before the Court could decide it, the relatively short time left before the injunction will have been fully carried out vitiates any need for review by this Court.

Nonetheless, the private parties who intervened below, led by Monsanto Co., the owner of the patents on GE alfalfa, have sought review.[1] According to Monsanto, the case presents the questions whether NEPA plaintiffs are "specially exempt" from showing likely irreparable injury to obtain an injunction; whether a district court may dispense with an evidentiary hearing to resolve "genuinely disputed facts directly relevant to the appropriate scope of [a] requested injunction"; and whether an injunction may be issued "to remedy a NEPA violation based on only a remote possibility of reparable harm." Pet. i.

None of these three questions is properly presented, because the correctness of the decision below does not depend on resolution of any of them. The court of appeals did *not* hold that NEPA plaintiffs are "specially exempt" from showing a likelihood of irreparable injury, nor did it affirm the injunction based only on the existence of a "remote possibility" of "reparable" harm. Rather, the court expressly held that the traditional test for issuance of injunctive relief—including the requirement of irreparable injury—was fully applicable to environmental cases. *See* Pet. App. 11a-12a. Based on its review of the extensive record, it affirmed the district court's finding that respondents had demonstrated a sufficient *likelihood* of *irreparable* injury (in the form of genetic contamination of conventional and organic alfalfa crops) to justify permanent injunctive relief. Pet. App. 13a.

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[1] For convenience, we refer to the petitioners collectively as "Monsanto."

Moreover, the court of appeals did not hold that a district court may forgo an evidentiary hearing when there are genuine evidentiary disputes that are "directly relevant" to the scope of injunctive relief. Rather, it held that the issues Monsanto claimed required additional presentation of evidence were *not* material to the scope of relief in the particular circumstances of this case, and that the procedures employed by the district court (which included multiple hearings as well as extensive review of documentary evidence and declarations) were adequate to support its determination that the scope of the injunction was necessary to prevent irreparable injury. Pet. App. 17a.

The court of appeals' application of the standards for issuance of injunctive relief does not conflict with decisions of this Court or any other court of appeals, nor has any court held that an evidentiary hearing is required in circumstances comparable to those here. The correctness of the decision below is thus no more than a factbound question involving a distinctive set of circumstances set forth in an extensive record that has already been thoroughly reviewed by two courts, both of which reached the same conclusions. Review of such a fact-specific decision is particularly unwarranted given the ephemeral nature of the dispute in this case.

STATEMENT

1. Background of the Lawsuit

This case originated as a challenge to a decision of the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) to deregulate the

use of GE alfalfa—a decision reached without the benefit of an EIS.

Alfalfa, the fourth most widely grown crop in the U.S., is open-pollinated by wild and farm-raised bees, which can carry alfalfa pollen from one plant to another over long distances. Pet. App. 6a, 35a. A perennial crop, alfalfa is only replanted every three to four years. Alfalfa is considered the best available animal feed for ruminants and consequently the dairy and beef cattle, sheep, chicken and turkey livestock sectors rely on alfalfa as feed. About 7% of alfalfa seed is eaten by people in the form of sprouts. Organic and most conventional alfalfa "is grown without the use of any herbicides." Pet. App. 74a-75a.

Monsanto's GE alfalfa differs from all previously existing conventional alfalfa varieties in that its genome contains a "genetic construct" composed of DNA derived from three foreign plants (the petunia, the pea, and *Arabidopsis thaliana*), two bacteria (the plant pathogen *Agrobacterium* and *E. coli*), and a virus (the plant pathogen figwort mosaic virus). The genetic construct allows GE alfalfa to survive indiscriminate dousing of glyphosate, or "Roundup," a powerful non-selective herbicide that kills or severely damages most species of plants, including natural alfalfa. Pet. App. 28a. Unlike conventional plant breeding, the transformation is a "permanent modification of a plant's genetic makeup through genetic engineering." Pet. App. 45a.

Prior to APHIS's unrestricted nationwide deregulation, alfalfa farmers, exporters, experts, and others expressed a variety of concerns that commercialization of GE alfalfa would spread its genetic material

to conventional and organic alfalfa, threatening farmers' choice to grow and sell alfalfa free of unwanted transgenic contamination. Pet. App. 29a-30a; *see e.g.* ER 712, SER 127-28, 134, 142-45, 148, 156-58, 167-68. [2]

Such contamination would have significant and novel impacts. Conventional alfalfa exporters raised concerns of contamination, since two-thirds of the world requires that GE crops and foods be labeled and important alfalfa export markets ban GE crops. Pet. App. 30a, 40a; *see also* Pet. App. 172a; ER 403; SER 34-35, 38. Organic alfalfa farmers and organic dairies that rely on organic alfalfa as their main source of forage raised concerns because the organic standard prohibits, and organic consumers reject, genetic engineering. Pet. App. 38a, 40a; SER 100-02, 113, 117. Comments also expressed concerns regarding the unstudied environmental impacts of the development of glyphosate-resistant weeds. Pet. App. 30a; *see e.g.*, SER 139, 149, 150-51, 156-66. Since the introduction of "Roundup Ready" GE crops, glyphosate use has increased five-fold, leading to increased resistance to it among weeds. SER 135. Finally, comments raised concerns about impacts based on the increased use of glyphosate on protected species and the environment. Despite these concerns, APHIS found that deregulation of GE alfalfa would have no significant environmental impacts and thus

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[2] Citations to the large portions of the record below that are omitted from the evidentiary materials in the appendix to Monsanto's petition are to the Excerpts of Record (ER) and Supplemental Excerpts of Record (SER) filed in the Ninth Circuit.

unconditionally deregulated it without preparing an EIS.

2. The Summary Judgment Ruling

Respondents sued to set aside the deregulation of GE alfalfa, contending that the finding that GE alfalfa would have no significant environmental impact was arbitrary and capricious and hence that the failure to conduct an EIS violated NEPA. Although the administrative record documented cross-pollination at distances of several miles, Pet. App. 29a, 6a, the government took the position that respondents' concerns about genetic contamination of conventional and organic alfalfa crops were irrelevant under NEPA. Indeed, according to the government, genetic contamination would not amount to an impact requiring analysis *even if it completely wiped out all organic and other non-GE alfalfa*. Pet. App. 42a.[3] Consequently the government argued that APHIS had correctly declined to study potential impacts stemming from contamination or potential measures to contain it. Pet. App. 39a, 61a, ER 673.

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[3] The government made its position painfully clear during argument on motions for summary judgment:

> The Court: So they are positing a case in which they believe that the introduction of the organic—I mean, of the genetically engineered alfalfa will actually eliminate organic alfalfa. And you're coming back and saying, without saying whether it will happen or not, if it did happen, that would not qualify. So what. I mean, too bad. That's the way life is. And so what. Because that still doesn't result in an environmental, a significant environmental impact, the elimination of all organic alfalfa.
>
> [APHIS counsel]: Yes, your honor."

Transcript, Jan. 19, 2007, at 52-53.

The district court granted summary judgment in favor of respondents. The court found that respondents had shown a likelihood that use of GE alfalfa would result in contamination of conventional and organic alfalfa either through cross-pollination or mixing of seed. Pet. App. 35a. Indeed, APHIS had conceded that such effects could occur (*e.g.*, Pet. App. 36a, 38a, 45a), and the court found that the agency's efforts to disregard the impacts of such contamination were unfounded and did not reflect the "hard look" at environmental consequences required by NEPA. Pet. App. 38a-41a.

The court held that "the contamination of conventional and organic alfalfa with the Roundup Ready gene is itself an impact that is harmful to the human environment." Pet. App. 61a; *see also id.* at 44a-45a. The court found that genetic contamination would have severe negative effects on growers of conventional and organic alfalfa, and it rejected APHIS's legal argument that such effects were not impacts within the meaning of NEPA. Pet. App. 41a-45a.[4] Accordingly, the district court held that APHIS had violated NEPA by deregulating GE alfalfa without first conducting an EIS. Pet. App. 52a. No party challenged that ruling on appeal.

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[4] Similarly, the court held arbitrary and capricious APHIS's failure to analyze the development of Roundup-resistant weeds, the cumulative impacts of GE alfalfa's deregulation with those of other GE crops, and the concomitant increased use of glyphosate, and ordered these impacts be studied in the EIS. Pet. App. 46a-48a.

3. The Remedy Phase

Following its summary judgment ruling, the district court spent nearly three months considering the appropriate remedy. Respondents sought not only an order setting aside APHIS's deregulation of GE alfalfa and requiring the preparation of an EIS, but also injunctive relief that would prevent the unrestricted use of GE alfalfa pending completion of an EIS and a new decision by the agency. APHIS, by contrast, proposed that the use of GE alfalfa continue pending the EIS under conditions similar to those Monsanto had previously imposed on its use by contract, which would result in a five-fold increase in planting of GE alfalfa. Pet. App. 64a. Monsanto intervened to support APHIS's proposals.

In support of their requested injunction, respondents submitted evidence (in addition to the administrative record evidence) that genetic contamination was likely under the conditions proposed by APHIS and, indeed, that contamination had *already occurred* when GE alfalfa was planted under conditions substantially similar to those proposed by APHIS. Pet. App. 13a, 70a-71a. Respondents' submissions documented contamination in alfalfa fields in the western United States. SER 16-19, 20-21, 23-26, 27, 29-32, 45, 65, 71; ER 115, 117, 118, 135, 138.[5] More-

[5] For example, the seed fields of Dairyland Seed Company, Inc., a major alfalfa seed producer, were contaminated at eleven to sixteen sites at distances up to 1.5 miles from GE alfalfa plantings; this contamination occurred despite isolation distances required by Monsanto. SER 19-21, 27, 29-30, 31-32. Similarly, fields of Cal/West Seeds, a farmer-owned cooperative and major alfalfa seed exporter, were contaminated in California and Wyoming. SER 44-46.

over, respondents' evidence demonstrated that contamination risks were not limited to bee-mediated cross-pollination; rather, contamination can and does occur in many other ways, including through seed mixing and spillage, dormant hard seed, forces of nature (such as storms), irrigation ditches, substandard stewardship practices, and human error. SER 18-19, 32, 60-61, 82, 95-97, 106, 121.

Respondents' evidence of actual contamination was not contested by the government. Pet. App. 71a. Monsanto, for its part, contested *how* the contamination had occurred, but not *that* it had occurred. *See* Pet. App. 405a-06a, 408a. Indeed, Monsanto itself submitted an expert study that found high rates of contamination at a distance of nearly two miles from GE alfalfa plantings. ER 424-29; SER 18, 23-26, 65.[6]

The district court held two hearings on the issue of permanent injunctive relief, and at one of them permitted the president of petitioner Forage Genetics to address the court with respect to factual matters. Significantly, that statement undermined Monsanto's contention that forage alfalfa poses no threat of bee-mediated cross-pollination because it is harvested before it flowers: The witness acknowledged that farmers often could not harvest before flowering

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[6] The same scientist who conducted this study also stated his opinion "that in order for there to be *zero* tolerance of any gene flow between a Roundup Ready alfalfa seed field and a conventional seed field, those fields would have to have a five-mile isolation distance between them." ER 113 (original emphasis). Respondents also introduced evidence that wild bees in the natural environment, such as bumblebees, feral honeybees, and other pollinators, travel and cross-pollinate at distances of several miles. SER 25, 62, 64-65, 67, 74, 97, 123-24, 169-70.

because of weather conditions. *See* Pet. App. 70a-71a, 62a.

4. The Permanent Injunction

Monsanto, but not APHIS, requested a full-blown evidentiary hearing on the environmental effects of GE alfalfa before the court ruled on the scope of its remedy. Declining to conduct a hearing that would replicate the scientific inquiry required of the agency in conducting the EIS, *see* Pet. App. 68a, the district court found, upon consideration of the arguments and statements made at the hearings together with the voluminous evidentiary materials submitted by all parties, that respondents had shown a sufficient likelihood of irreparable injury to warrant an injunction against further planting of GE alfalfa, as opposed to the narrower injunction advocated by APHIS and Monsanto. Critical to the court's finding was the uncontested evidence that genetic contamination had already occurred under conditions of planting equivalent to those advocated by Monsanto and APHIS. Pet. App. 70a-71a. The court also stressed that APHIS's proposal would greatly increase the likelihood of additional contamination because it would increase the usage of GE alfalfa *five-fold*, and that APHIS acknowledged that it would lack the resources to enforce the usage conditions it advocated even if planting remained at its current levels. Pet. App. 70a.

Nonetheless, the court declined to issue a blanket injunction. Although respondents sought to enjoin the harvesting of any seed from alfalfa already planted as well as any future planting, the court carefully balanced the equities and chose a middle course that maintained the status quo. The injunc-

tion barred the future planting of GE alfalfa but permitted the continued growing and harvesting of GE alfalfa already in the ground under conditions proposed by APHIS and adopted by the court. Pet. App. 76a-77a, 10a.[7]

With regard to future planting, however, the court held that "the harm to farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to [petitioners] and those farmers wishing to switch to [GE alfalfa]." Pet. App. 71a. With respect to harm to Monsanto, the court emphasized that GE alfalfa accounted for little of its revenue and that, because alfalfa seed can be stored for years, Monsanto would be able to sell existing supplies in the future if APHIS ultimately approved its use. Pet. App. 72a. The court also found that the public interest supported delaying the further introduction of genetically altered alfalfa until APHIS studied its impacts. Pet. App. 75a.

5. The Appeal

Monsanto and the federal defendants appealed the scope of the permanent injunction, but not the finding of a NEPA violation. A panel of the Ninth Circuit affirmed, Pet. App. 80a-103a, and, after Monsanto (but not the federal defendants) sought rehearing or rehearing en banc, reissued its opinion with minor modifications. Pet. App. 1a-26a.

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[7] The court had already, in granting preliminary injunctive relief, allowed farmers who had purchased seed a window of opportunity to plant it before the court issued its permanent injunction. Pet. App. 58a.

The court, applying the traditional four-part test for the issuance of permanent injunctive relief, held that respondents had shown a sufficient likelihood of irreparable injury to warrant the relief granted. Pet. App. 11a-13a. The court of appeals rejected the government's and Monsanto's argument that the district court had improperly presumed the existence of irreparable injury and held that the district court's finding of irreparable injury was supported by the evidence that genetic contamination was not only likely under the conditions advocated by Monsanto, but had already occurred. Pet. App. 13a. The court further rejected Monsanto's claim—which was not supported by the government—that the district court should have held an evidentiary hearing. Acknowledging that an evidentiary hearing is normally required when there are material issues of fact going to the propriety of injunctive relief, Pet. App. 17a, the court held that the facts Monsanto desired to dispute were not material to the question of likely irreparable injury, but rather went to the merits of the scientific issues the agency was required to consider in the EIS. Pet. App. 18a.

6. The Ongoing Agency Proceedings

Although the government joined Monsanto in appealing the scope of the injunction, it did not, as noted above, appeal the holding that an EIS was required. Instead, it began preparing the EIS, the first it has ever done for any GE crop. APHIS released a draft EIS on December 14, 2009,[8] and published for-

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[8] *See* www.aphis.usda.gov/newsroom/content/2009/12/alfalfa.shtml.

mal notice of it in the Federal Register four days later. 74 Fed. Reg. 67206 (Dec. 18, 2009) (EIS No. 20090435). The comment period on the draft EIS will close on February 16, 2010, after which the agency will finalize the EIS and issue a new "record of decision" on whether to deregulate GE alfalfa. At that point, the injunction will dissolve.

REASONS FOR DENYING THE WRIT

I. Review Is Unwarranted in Light of the Impending Completion of the EIS.

The injunction in this case was a "permanent" one, as distinct from a "preliminary" or "interlocutory" one, in that it was the relief granted to implement a final, merits disposition of the claims in the case. Although permanent in that sense, it is at the same time ephemeral in that it neither requires nor prohibits anything further once the government completes its EIS and issues a new decision on the deregulation of GE alfalfa. In particular, the injunction's prohibitions on planting alfalfa operate only "[u]ntil the federal defendants prepare the EIS and decide the deregulation petition." Pet. App. 108a. Thus, the challenged provisions of the injunction expire by their own terms once the government takes the required actions.

The agency has now completed the draft EIS and is proceeding to finalize it and issue a new decision. When that process is completed—likely in the spring, summer or fall of 2010—the permanent injunction will impose no further requirements or limitations on anyone, and whether (or under what circumstances) it will be permissible to plant GE alfalfa will depend

not on the scope of the injunction, but on the agency's new decision about the crop's regulatory status.

At that time, the issues Monsanto raises will be moot. An injunction's propriety is a moot question once "'the terms of the injunction ... have been fully and irrevocably carried out.'" *Honig v. Students of Cal. Sch. for the Blind*, 471 U.S. 148, 149 (1985) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 398 (1981)). Although *Honig* and *Camenisch* involved preliminary injunctions, the same principle holds where compliance with a court's permanent injunction has "completely cured" the violation of law that gave rise to the plaintiffs' claim. *County of Los Angeles v. Davis*, 440 U.S. 625, 633 (1979).

Thus, lower federal courts have held that a federal agency's compliance with an injunction ordering preparation of an EIS or similar action moots the question of the injunction's propriety. In *Village of False Pass v. Clark*, 733 F.2d 605, 612 (9th Cir. 1984), the court held that an agency's preparation of a Supplemental EIS mooted its cross-appeal of the injunction requiring the Supplemental EIS, and in *Romero-Barcelo v. Brown*, 643 F.2d 835 (1st Cir. 1981), the court held that the completion of an EIS mooted issues relating to the scope of the district court's order requiring the EIS.[9] Similarly, in *Sierra Club v. Glickman*, 156 F.3d 606, 619 (5th Cir. 1998), the court held that an agency's compliance with a

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[9] This Court reversed a separate part of the First Circuit's decision in *Romero-Barcelo* but left intact the lower court's holding that the preparation of the EIS mooted issues about permanent injunctive relief for the claimed NEPA violation. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 308 n.2 (1982).

court order requiring it to submit a Biological Opinion to the Fish & Wildlife Service under the Endangered Species Act mooted its appeal of that order. *See also Jersey Cent. Power & Light Co. v. New Jersey*, 772 F.2d 35, 40 (3d Cir. 1985) (state's compliance with an order preventing it from interfering with rail shipments of nuclear material mooted its appeal of the order); *Sannon v. United States*, 631 F.2d 1247, 1251 (5th Cir. 1980) (government's compliance with a permanent injunction requiring it to inform asylum seekers of rights for a six-month period mooted its appeal of the injunction).

In short, by the time this case could be heard and decided on the merits by this Court, the issue of the scope of the permanent injunction would very likely be mooted by the government's completion of its no-longer-contested obligation to prepare an EIS before deciding the status of GE alfalfa.[10] Even if it were not moot, the question by that point would most likely have been reduced to whether the prohibition on planting would continue for a few more weeks or months—an issue of minor importance at best and not worthy of this Court's review.

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[10] The issue would not be "capable of repetition, yet evading review." Issues about injunctive relief in NEPA cases do not, as a general matter, evade appellate (or Supreme Court) review, because the government controls the timing of the EIS's preparation and can proceed at a pace that allows it to fully exhaust appellate review. *See, e.g., Winter v. NRDC*, 129 S. Ct. 365 (2008); *Dep't of Transp. v. Public Citizen*, 541 U.S. 752 (2004). An injunction in a NEPA case thus is not "the sort of action which, by reason of the inherently short duration of the opportunity for remedy, is likely forever to 'evad[e] review.'" *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 481 (1990).

II. The Court of Appeals Correctly Applied the Standard for Issuance of Permanent Injunctive Relief, and Its Decision Does Not Conflict with Decisions of This Court or Other Courts of Appeals.

Monsanto contends that the court of appeals held that NEPA cases are "specially exempt" from the requirement that injunctive relief issue upon a showing of likelihood of irreparable injury (Pet. i) and accuses the Ninth Circuit of "outright defiance" of this Court's recent holding in *Winter v. NRDC*, 129 S. Ct. 365. Pet. 34. Monsanto's argument rests on a distortion of the court of appeals' decision and the jurisprudence of the Ninth Circuit more generally.

A. The Lower Courts Applied the Correct Standard in this Case.

Far from holding NEPA cases exempt from the ordinary standards for issuance of injunctive relief, the court of appeals stated straightforwardly that:

> To obtain permanent injunctive relief, a plaintiff must show "'(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'"

Pet. App. 11a (quoting *N. Cheyenne Tribe v. Norton*, 503 F.3d 836, 843 (9th Cir. 2007) (quoting *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006))).

The court emphasized that "[t]his traditional balancing of harms applies in the environmental con-

text," Pet App. 11a, and it cited previous Ninth Circuit opinions (predating *Winter*) holding that claimed environmental injuries in NEPA cases do not always justify injunctive relief. *See, e.g., Lands Council v. McNair*, 537 F.3d 981, 1005 (9th Cir. 2008) (en banc). Moreover, while noting that this Court has held that injunctions are usually appropriate in environmental cases "*if injury is found to be sufficiently likely*," Pet. App. 11a (emphasis added) (citing *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987)), the Court also recognized that "courts cannot grant or deny injunctive relief categorically in place of applying the four-factor test." Pet App. 12a (citing *eBay*, 547 U.S. at 394). At no point did the court even suggest that injunctive relief could be granted based on the "mere possibility of injury" standard rejected in *Winter*.[11]

Significantly, the court's recognition of the applicability of the traditional standard, including the likelihood of irreparable injury, was no mere afterthought thrown into its amended opinion following Monsanto's petition for rehearing and this Court's decision in *Winter*. Exactly the same description of

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[11] The court's statement that it is "unusual" to deny injunctive relief in a case where a NEPA violation has been found, Pet. App. 12a, reflects not the application of a different standard, but the court's empirical view that in most such cases the traditional standard will be satisfied because there will be a likelihood of irreparable environmental harm. *Cf. eBay*, 547 U.S. at 396 (Kennedy, J., concurring) ("To the extent earlier cases establish a pattern of granting an injunction ... almost as a matter of course, this pattern simply illustrates the result of the four-factor test in the contexts then prevalent. The lesson of the historical practice, therefore, is most helpful and instructive when the circumstances of a case bear substantial parallels to litigation the courts have confronted before.").

the governing standard appeared in the court's original opinion two months before *Winter*. Pet. App. 89a.

Having stated the correct standard, the court of appeals did not then proceed, as Monsanto suggests, to ignore it. Rather, its affirmance of the district court's decision with respect to the scope of the injunction rested on its determination that the district court had properly found that irreparable injury would be likely under the narrower injunction advocated by Monsanto—a finding that rested in large part on the fact that genetic contamination had already occurred when GE alfalfa was used under substantially the same conditions proposed by APHIS and Monsanto:

> With respect to harm, the court found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place that were similar to their proposed mitigation measures. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. The court also reasoned that appellants would be unable to enforce compliance with any proposed mitigation measures, given the government's admitted lack of resources. The court therefore did not presume that irreparable harm was likely to occur only on the basis of the NEPA violation; it concluded that plaintiffs had established that genetic contamination was sufficiently likely to occur so as to warrant broad injunctive relief,

> though narrower than the blanket injunction sought by plaintiffs.

Pet. App. 13a.

As this passage makes clear, and contrary to Monsanto's assertion, the court did not ignore *Winter* by failing to "evaluate whether there would be a likelihood of irreparable harm" under a more narrowly tailored injunction "with APHIS's proposed stewardship measures in place." Pet. 29-30. Rather, the court specifically concluded that irreparable injury was likely under the conditions proposed by the government and Monsanto *because it had already occurred under those conditions*.

That the court of appeals acted properly in affirming the district court's order is underscored by the district court's own correct analysis and application of the legal standards governing issuance of injunctive relief. Like the court of appeals, the district court recognized that "[u]pon a finding of a NEPA violation an injunction does not automatically issue." Pet. App. 65a. Rather, the court must "engage in the traditional balance of harms analysis, even in the context of environmental litigation." Pet. App. 65a (quoting *Forest Conservation Council v. U.S. Forest Service*, 66 F.3d 1489, 1496 (9th Cir. 1995)). Although the court noted that where environmental harm is present an injunction is generally appropriate because such harm is typically irreparable, *see id.*, it did not suggest that an injunction could be granted in the absence of such injury, nor did it even allude to the "mere possibility" standard.

And, as the Ninth Circuit stated, the district court found a likelihood of irreparable injury based on (1) the fact that damage to conventional and or-

ganic alfalfa had already occurred despite the measures Monsanto urged the court to adopt instead of preserving the status quo, and (2) the failure of Monsanto's proffered evidence to provide a basis for concluding that such damage would not continue to occur, especially given the five-fold expansion in the use of GE alfalfa that was expected if planting were allowed to continue. *See* Pet. App. 64a, 66a-67a, 69a-71a. As the court concluded:

> Such contamination is irreparable environmental harm. The contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa. Moreover, it is not a one season loss; alfalfa is a perennial crop and once removed cannot be replanted for two to four years.

Pet. App. 71a.

Monsanto's real complaint is not with the legal standard applied below but with the courts' *application* of the standard to find irreparable injury in this case. But even if Monsanto's arguments that the lower courts erred in evaluating the record and finding a likelihood of irreparable injury were convincing, such a factbound issue would be inappropriate for review by this Court. "A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." S. Ct. R. 10. In any event, Monsanto's claim of error is unconvincing: The contention that irreparable injury was not *likely* when it had *already occurred* under the same conditions of use that Monsanto wanted to have included in the injunction is, to say the least, not one that merits plenary consideration by this Court.

B. The Finding of Injury in this Case Does Not Conflict with Decisions of Other Circuits.

Monsanto attempts to conjure up a conflict between the lower courts' finding of irreparable injury in this case and a handful of decisions of other courts that have declined to find irreparable injury in certain cases involving claims of injury to wildlife populations. Specifically, Monsanto contends that the determination that genetic contamination affecting crops raised by conventional and organic alfalfa farmers constituted irreparable injury conflicts with statements by some courts that in ESA cases or other cases where the claimed environmental harm is a threat to a wildlife population, injury to individual members of a species is not irreparable injury unless it threatens the survival of the species itself. Pet. 33 (citing *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975), and *Water Keeper Alliance v. U.S. Dep't of Defense*, 271 F.3d 21, 34 (1st Cir. 2001)).

Whatever the merits of the decisions Monsanto cites may be, they do not even remotely conflict with the decision in this case. The notion that "species-level" injury must be shown to obtain an injunction in an ESA case or one making similar claims of harm, though not fully explained in the few cases that so hold, apparently rests on two premises: (1) the ESA is concerned with species preservation, and thus harms to individual animals that have no impact on the species are not a significant injury in a case brought under the ESA; and (2) the plaintiffs in such cases are not members of the endangered species, but human beings who seek to view or study them, and deaths of individual animals that have no

impact on the abundance of the species are unlikely to injure the plaintiffs' opportunity to view or study the species.

Both of these rationales, even if correct, are specific to ESA cases and other cases involving claims resting on an alleged injury to a population of animals or plants and have no application here. Nothing in the decisions Monsanto cites suggests that the injury suffered by *farmers* who grow conventional or organic alfalfa when their crops are genetically contaminated does not "count" unless the injury threatens alfalfa at a species-wide level. Unlike someone who wishes to view wildlife, and may be unaffected by the death of a single member of an abundant species, a farmer whose crop is ruined suffers an injury regardless of whether *alfalfa* has suffered at a "species level." It is therefore not surprising that Monsanto is able to cite *no* decisions from any court applying the species-level harm rationale to facts comparable to those here. *Cf. Greater Yellowstone Coalition v. Flowers*, 321 F.3d 1250, 1256-58 (10th Cir. 2003) (declining to require species-level injury in a case involving non-ESA claims). Moreover, Monsano's observation that the United States identified a "circuit split" over the requirement of species-level harm as among the reasons it sought review in *Winter* (see Pet. 33-34) is no reason for granting certiorari in a case where the issue is not implicated.

In any event, the lower courts' holding that the harm here is irreparable is well-supported by this Court's teachings. *Amoco*, 480 U.S. at 545 ("Environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, i.e., irrepara-

ble."). The harm is irreparable because it cannot be adequately remedied by money damages and is permanent: The district court found that "[o]nce the gene transmission occurs and a farmer's seed crop is contaminated with the Roundup Ready gene, there is no way for the farmer to remove the gene from the crop or control its further spread." Pet. App. 36a. Contamination permanently alters the genetic makeup of the crop, eliminating the farmers' ability to choose the crop he wishes to sow: "[I]t cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa." Pet. App. 71a. Moreover, the injury is not a one-season loss; once removed, alfalfa cannot be replanted for two to four years. *Id.*

C. The Ninth Circuit Has Not Engaged in a "Brazen" Campaign of "Defiance" of *Winter v. NRDC.*

Citing two other Ninth Circuit decisions that it says misapplied *Winter*, Monsanto accuses the Ninth Circuit of "brazen" acts of "outright defiance" of *Winter* and urges the Court to grant certiorari or summarily reverse to punish the lower court. Pet. 34. But whatever the Ninth Circuit may have done in other cases, it did not apply the "mere possibility" standard or otherwise refuse to follow *Winter* in *this* case. Its rulings in other cases cannot justify reversal in this one.

Moreover, the Ninth Circuit's case law since *Winter* shows that Monsanto's depiction of a circuit in open revolt against this Court's rulings is not just hyperbolic but outright false. Between the time *Winter* was decided and this writing, the Ninth Circuit has cited *Winter* in more than twice as many cases as

the other 12 circuits combined. The court has squarely acknowledged that *Winter* significantly changes the standard applicable to claims for injunctive relief in the Ninth Circuit:

> [W]e must follow the Supreme Court's recent expatiation on the proper standard for granting or denying [injunctive] relief. *See Winter v. Natural Res. Def. Council, Inc.*, __ U.S. __, 129 S. Ct. 365 (2008). In *Winter*, the Court reversed one of our decisions, which, it determined, upheld a grant of a preliminary injunction by use of a standard that was much too lenient. *Id.* at __, 129 S. Ct. at 370. As the Court explained, an injunction cannot issue merely because it is possible that there will be an irreparable injury to the plaintiff; it must be likely that there will be. *Id.* at __, 129 S.Ct. at 375. ... To the extent that our cases have suggested a lesser standard, they are no longer controlling, or even viable.

American Trucking Assns. v. City of Los Angeles, 559 F.3d 1046, 1052 (9th Cir. 2009); *accord, e.g., Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1126-27 (9th Cir. 2009); *Johnson v. Couturier*, 572 F.3d 1067, 1081 (9th Cir. 2009).

The Ninth Circuit's decisions show that it is not merely paying lip-service to *Winter*. In *Stormans*, for example, the court reversed and remanded a preliminary injunction because the lower court's balancing of the equities had rested on the "mere possibility" standard. *See* 586 F.3d at 1138. The court has also relied on *Winter* to uphold the denial of relief in environmental cases. *See Humane Soc'y of U.S. v. Gutierrez*, 558 F.3d 896 (9th Cir. 2009); *Tongass Conservation Soc'y v. Cole*, 2009 WL 2750725 (9th

Cir. Aug. 31, 2009). And in *Sierra Forest Legacy v. Rey*, 577 F.3d 1015 (9th Cir. 2009), a NEPA case, the court made clear that it did not view the grant of injunctive relief in a meritorious NEPA case as automatic, but remanded to the district court for an analysis of the likelihood of irreparable injury and the balance of equities in light of the proposed narrow tailoring of injunctive relief, consistent with *Winter*. *See id.* at 1022-24.

Monsanto offers only two examples of the Ninth Circuit's supposed defiance: *Nelson v. NASA*, 568 F.3d 1028 (9th Cir. 2009), and the unpublished decision in *Greater Yellowstone Coalition v. Timchak*, 323 Fed. Appx. 512 (9th Cir. 2009). As to *Nelson*, Monsanto cites the statement of a dissenting judge that the panel did not consider the public interest in holding that a preliminary injunction was required. *See* 568 F.3d at 1050 (Kleinfeld, J., dissenting from denial of rehearing en banc). But Monsanto does not claim that the lower courts did not consider the public interest in *this* case (or, indeed, that this factor is generally overlooked in the Ninth Circuit), so the claimed error in *Nelson* hardly provides support for review (let alone summary reversal) here. In any event, as the judges concurring in the denial of rehearing in *Nelson* pointed out, the panel's decision *did* consider the public interest in balancing the equities. *See id.* at 1030 (Wardlaw, J., concurring). Moreover, although the United States has filed a petition for certiorari in *Nelson*, it does not contend that the Ninth Circuit failed to follow *Winter*, but only that the court erred in finding a likelihood of merit in the constitutional claims in that case. *See*

Pet. for Cert., *NASA v. Nelson*, No. 09-530 (filed Nov. 2, 2009).

Monsanto's citation of *Timchak* is equally unpersuasive. Monsanto quotes a snippet of that nonprecedential opinion out of context, but does *not* quote the key passage in which the court expressly acknowledged that "*Winter* held that it is not sufficient for a plaintiff to show a mere possibility of irreparable harm in order to prevail on his request for preliminary injunctive relief." 323 Fed. Appx. at 514 n.1. *Timchak* granted a temporary stay and remanded for further consideration only because the district court had erroneously refused to consider some of the irreparable injuries the plaintiffs claimed would necessarily be caused by the mining activities they sought to enjoin.

III. The Court of Appeals' Holding That the District Court Was Not Required to Hold an Evidentiary Hearing in the Specific Circumstances of this Case Does Not Merit Review.

Monsanto devotes much of its petition to arguing that the Ninth Circuit's affirmance of the district court's decision not to receive oral testimonial evidence on the scope of the permanent injunction presents an issue that requires this Court's review. Monsanto contends that this issue is of substantial importance to the United States because of the large numbers of NEPA cases the government loses. Pet. 22. The government, apparently, sees it differently, as it did not argue at *any* point in the proceedings that the district court should hold (or should have held) an evidentiary hearing, and the government

has chosen not to seek review in this Court on that ground or any other.

Monsanto, moreover, offers no reason for the Court to review the factbound question whether an evidentiary hearing was necessary under the specific circumstances of this case. Strikingly, Monsanto cites no decision from any other court that disagrees with the Ninth Circuit's statement that a court in a NEPA case need not hold an evidentiary hearing to replicate the scientific analysis that the agency will conduct in carrying out its EIS; indeed, Monsanto cites no decisions that even address that question.

Instead, Monsanto attempts to suggest that not holding an evidentiary hearing in this case amounts to creating a "presumption" of irreparable injury or an "automatic" right to an injunction in NEPA cases, in violation of this Court's teachings in such cases as *Winter*, *eBay*, *Romero-Barcelo*, and *Amoco*. Monsanto's argument, however, conflates the question whether a finding of likely irreparable injury is necessary—the issue addressed in those four cases and faithfully followed by the courts below—with the question of the procedures necessary to make that finding in a particular case, which the cited cases do not address.

The lower courts' holding on that procedural issue was not, as Monsanto suggests, a shocking departure from principles ordinarily applied by other federal appellate and trial courts. Rather, the opinions of the Ninth Circuit and the district court show that their review of the record disclosed no genuine dispute of fact over the material issue of *whether* irreparable injury was likely, given, among other things: the undisputed NEPA violation; the government's failure to

provide analysis regarding the efficacy of its proposed mitigation measures; the uncontested record of decision evidence that bees cross-pollinate at distances of several miles (Pet. App. 29a, 35a), further than the isolation distances proposed by APHIS; the acknowledged lack of agency resources to enforce the proposed remedial measures at current levels of planting, let alone the five-fold increase contemplated by the government's proposal; and the undisputed evidence of genetic contamination that had already occurred under the conditions of use proposed by the government and Monsanto.

The district court merely declined to hold a full-blown trial to resolve further scientific issues concerning the degree of environmental impact of GE alfalfa—a trial that both the court of appeals and the district court considered particularly unwarranted because the whole point of NEPA is to require the *agency* to resolve those issues in the first instance through the preparation of an EIS, and because the injunctive relief ordered would last only until that analysis had been carried out. *See* Pet. App. 16a-20a, 67a-68a; *see also Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 831 (9th Cir. 2002); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989) (NEPA "ensures that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts.").

The court of appeals' affirmance of the district court does not, as Monsanto contends, conflict with decisions calling for evidentiary hearings where the issuance of a permanent injunction requires resolution of disputed issues of material fact that turn on

conflicting testimony. Indeed, the court of appeals made clear that it was in full agreement with the holding of *United States v. Microsoft*, 253 F.3d 34, 101 (D.C. Cir.), *cert. denied*, 534 U.S. 952 (2001), which Monsanto acknowledges is "the leading modern case." Pet. 25; *see* Pet. App. 17a (citing *Microsoft*). The court of appeals merely held, sensibly enough, that what facts are material to the issuance of injunctive relief in a NEPA case depends in part on the nature of the claim and the scope and duration of the relief requested. *See id.* ("The district court did not believe defendants had established any material issues of fact that were in dispute in the case before the court. Rather, it viewed the disputed matters to be issues more properly addressed by the agency in the preparation of an EIS.").

Nor was this a case where a party was denied the chance to be heard. The district court held two hearings on the scope of relief, and received an extensive oral statement from petitioner Forage Genetics' president. Transcript, March 8, 2007, at 14-29, 55-57. At the first hearing the judge told the intervenors: "I will listen to anybody who's—you know, anybody you suggest that I should hear on the subject, I will be glad to hear them." Transcript, March 8, 2007, at 13. The court noted that it had "carefully reviewed" all of the voluminous evidentiary submissions and detailed written direct testimony submissions from the intervenors. Pet. App. 9a, 67a. The judge stated:

> I've read the Declarations. I appreciate that this could have been the subject of live testimony, but I thought the declarations were certainly

> comprehensive in stating the facts as the declarant knew them to be.

Transcript, April 27, 2007, at 9.

Still further afield is Monsanto's suggestion that the court of appeals' decision creates a conflict among the circuits over the circumstances under which an evidentiary hearing is necessary before issuance of a *preliminary* injunction. *See* Pet. 27, 28. That issue was not before the Ninth Circuit, and it did not purport to opine on it. The court's reference to the anticipated duration of the injunction in this NEPA case was not intended to suggest that the procedures for issuing it should mirror those for a preliminary injunction, but was a part of the court's rationale for concluding that, given the finding of a likelihood of irreparable injury, further details as to the scope of environmental harm threatened by GE alfalfa that would shortly be resolved by the agency itself did not require resolution before issuance of final injunctive relief. The logic of this rationale is now apparent, as APHIS has released the draft EIS, and all interested parties will now have extensive input into the future of GE alfalfa in the NEPA process, based on a new administrative record in which the agency has, for the first time, assessed the crop's potential significant impacts. Once that process is complete, the injunction will be dissolved.

In short, the precedents cited by Monsanto concerning the general subject of procedures for issuing permanent and temporary injunctions fall far short of evincing a conflict among the circuits over whether an evidentiary hearing is required on the scope of permanent injunctive relief in a NEPA case presenting circumstances analogous to those here. Monsanto

proffers only a single decision in an attempt to demonstrate the existence of such a conflict: the twenty-year-old opinion of the Second Circuit in *Town of Huntington v. Marsh*, 884 F.2d 648 (2d Cir. 1989), *cert. denied*, 494 U.S. 1004 (1990). The Second Circuit's reasons for requiring an evidentiary hearing in *Huntington*, however, are inapplicable here.

Unlike this case, where the government did not contradict respondents' evidence that the practices the district court enjoined had actually resulted in environmental harm, *Huntington* was a case where the government offered substantial evidence that the activities the plaintiffs sought to enjoin had *not* caused harm to the environment. *See id.* at 653. Indeed, counsel for the *Huntington* plaintiffs conceded at oral argument before the Second Circuit that he did not contest the government's evidence. *Id.* The court held that the district court had erred in concluding "that the establishment of a statutory violation, without more, warranted an injunction" and in issuing an injunction in the face of the government's substantial evidence that the challenged actions had caused no injury. *Id.* at 654. But because the plaintiffs had introduced some evidence below suggesting a possibility of injury, the Second Circuit did not hold the plaintiffs to their attorney's concession that he did not contest the government's evidence, but ruled that they should be permitted an opportunity to overcome the government's evidence on remand in an evidentiary hearing.[12] *Id.* at 654.

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[12] The court did not specify whether the "evidentiary hearing" it referred to would require the introduction of oral testi-

(*Footnote continued*)

The decision below is fully consistent with *Huntington*. *Huntington* required an evidentiary hearing only because there was a genuine dispute over facts material to the existence of irreparable injury, which the courts below found not to be true in this case on the very different record before them. Nothing in *Huntington* remotely suggests that in a case such as this one, where the record establishes the existence of irreparable injury, the district court must nonetheless hold an evidentiary hearing replicating the inquiry into the environmental consequences of the agency's action that the EIS is supposed to encompass.

Once Monsanto's exaggerated claims of conflict are set aside, its assertion that an evidentiary hearing was necessary in this case stands revealed for what it is: a challenge to a highly fact-specific and eminently practical decision about the appropriate procedures for a particular case, turning on the specifics of the evidence of injury, the nature of the claim, and the scope and anticipated duration of the injunction. Particularly in light of the government's failure even to seek an evidentiary hearing in the case, let alone seek review by this Court of the failure to provide one, Monsanto's assertion that the issue is one of national importance requiring resolution by this Court rings hollow.

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mony or whether the district court could rule upon submissions of written evidence, as the district court did in this case.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

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Date: December 2009

REPLY BRIEF

FILED
DEC 23

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
PETITIONERS,

v.

GEERTSON SEED FARMS, ET AL.,
RESPONDENTS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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ARGUMENT

The government agrees with petitioners that the Ninth Circuit upheld what amounts to "a presumption in favor of a nationwide injunction" in NEPA cases. Brief of Federal Respondents ("U.S. Br.") 12. As the government has explained, that rule—which the Ninth Circuit embraced as the "correct legal standard"—"turn[s] the appropriate analysis on its head by assuming that ... an injunction is warranted halting the activity in question 'until the NEPA violation is cured.'" U.S. Br.12-13 (quoting Pet.App.55a). That rule can have potentially devastating consequences for private parties and the government alike. Indeed, the government recognizes that it resulted here in an injunction "requir[ing] APHIS to re-regulate RRA nationwide, notwithstanding APHIS's determination that RRA did not pose a plant pest risk and should no longer be regulated." U.S. Br.12 n.1. If allowed to stand, the Ninth Circuit's decision threatens to fundamentally upset the standards governing the entry of injunctive relief in essentially *any* NEPA case filed in that circuit. Especially given the Ninth Circuit's prior track record on this exceptionally important question (*i.e.*, the standards governing the entry of injunctive relief), *see Winter v. NRDC*, 129 S. Ct. 365 (2008), there is no reason for the Court to allow this profoundly misguided decision to take root. The Court should grant certiorari or, at a minimum, summarily reverse.

1. The government acknowledges (at 11-13) that the Ninth Circuit's decision in this case sustains a nationwide injunction that cannot be reconciled with this Court's precedents. Indeed, neither respondents nor the government makes any effort to defend the

Ninth Circuit's holding that the likelihood of irreparable harm is immaterial in NEPA cases whenever an agency will conduct additional environmental review that may bear on the issue. Pet.18-23.

Nor have they provided any good reason to leave this fundamentally flawed decision in place. That includes the suggestion of potential future mootness based on the publication of a final environmental impact statement ("EIS") at some point. To begin with, notwithstanding the government's rosy predictions, past practice strongly suggests that it is exceedingly unlikely that APHIS will publish a final EIS before this Court completes its Term in June. Comments on the draft EIS are not due until February 16, 2010, and that date may be extended. APHIS took four months to address comments on the earlier environmental assessment ("EA"), Pet.App.141a-42a—which was a far simpler document that drew much less attention (as one of dozens of similar deregulations, rather than a crucial part of the most prominent litigation of its kind[1]). And, of course, there is no possibility of mootness if this Court were simply summarily to reverse the decision below.

Respondents never really dispute that assessment. Their most optimistic prediction is that the final EIS will be released "likely in the spring, summer or fall of 2010," Brief of Geertson Seed Farms, *et al.* ("Opp.") 13—the latter two being after this Term ends. And the government notably makes no commitment to conclude

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[1] Respondents have urged "all concerned parties" to submit comments. *See* http://truefoodnow.org/2009/12/15/usda-again-aims-to-allow-unlimited-planting-of-genetically-engineered-alfalfa/ (last visited Dec. 29, 2009).

the EIS before the Term ends—nor does it even suggest that it could do so. *See* U.S. Br.10-11.

Even if APHIS were to release the EIS before June, though, this controversy would fall squarely within the "capable of repetition, yet evading review" exception to mootness. *FEC v. Wis. Right to Life, Inc.*, 551 U.S. 449, 462 (2007). Indeed, such repetition *has already occurred* in the same district court in a case with substantially similar claims led by a respondent here challenging APHIS's deregulation of genetically-engineered sugarbeets. *See Ctr. for Food Safety v. Vilsack*, No. 08-00484, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009). In that case, the district court also concluded that the government violated NEPA, ordered APHIS to prepare an EIS, and is now considering the very same remedial issues raised here, *see id.* at *9—with the plaintiffs relying heavily on the decision below to justify a nationwide injunction and oppose an evidentiary hearing. *See* Supplemental Joint Case Management Statement ("SJCMS"), *Vilsack*, at 7-15 (Nov. 23, 2009). The plaintiffs there seek to enjoin all planting of genetically-engineered sugarbeets, which constitute approximately 95% of all sugarbeets planted in the U.S. and *half* of the domestic sugar supply, without the district court conducting an evidentiary hearing. *Id.* at 5. As here, Monsanto intervened in those remedial proceedings, as the owner of the relevant intellectual property. *Id.* at 13. The issues presented here are therefore already repeating themselves in another case involving similar issues and similar parties, and more are in the offing as the Center for Food Safety has publicly committed "to halt the approval, commercialization or release of any new genetically engineered crops ... [and] advocat[e] the containment and reduction of existing genetically

engineered crops."[2] This amply satisfies the capable-of-repetition test, which requires only "a reasonable expectation that the same controversy involving the same party will recur." *See FEC*, 551 U.S. at 464.

If this petition is dismissed for fear of mootness, those future controversies are also likely to evade this Court's review. Petitioners successfully obtained expedited review in the Ninth Circuit—and yet it still has taken them 2½ years to get the case before this Court. Respondents do not suggest any other steps petitioners could have taken to hasten this litigation, and without expedited review injunctions in future cases are far more likely to expire before their legality can be tested. *See Davis v. FEC*, 128 S. Ct. 2759, 2669-70 (2008) (mootness exception applied because "despite the statute's command that the case be expedited ... claims could not reasonably be resolved before the election concluded") (quotations, alterations and citation omitted).

Respondents protest that the mootness exception cannot apply because the "government controls the timing of the EIS's preparation," citing *Winter* and *DOT v. Public Citizen*, 541 U.S. 752 (2004). Opp.15 n.10. But that fact is logically irrelevant—the government could not legitimately stall the EIS process to avoid mootness—and neither cited case even addresses mootness. Indeed, this Court granted review in *Winter* even though the agency was similarly in the midst of preparing an EIS. 129 S. Ct. at 386 (Breyer, J., concurring in part) (observing EIS would likely be completed two months later). There is no

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[2] *See* http://truefoodnow.org/campaigns/genetically-*engineered*-foods/ (last visited Dec. 29, 2009).

more reason here than in *Winter* to permit the Ninth Circuit's dangerous errors to evade review.

2. Respondents and the government argue that certiorari is unnecessary because the Ninth Circuit recited the proper four-factor injunctive relief standard. *See* Opp.16-18, U.S. Br.13; Pet.App.11a. But that court recited the right words in *Winter* as well, *NRDC v. Winter*, 518 F.3d 658, 677 (9th Cir. 2008), and as the government recognized in *Winter* that recitation provided little comfort, for *Winter* nonetheless fundamentally watered down the requirements for obtaining injunctive relief. The same goes here. As the government recognizes, the Ninth Circuit upheld the district court's application of a "presum[ption] [of] irreparable harm from the fact of APHIS's NEPA violation" rather than requiring the court to adjudicate the disputed material facts, U.S. Br.11-12—in direct contravention of this Court's precedents. U.S. Br.13.

Contrary to the government's suggestion (at 13), the Ninth Circuit's recidivism cannot be dismissed as a one-off mistake or inadvertent failure to appreciate that the district court had strayed from the governing law. In affirming the district court, the Ninth Circuit was reaffirming and extending its own prior holding in *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 831-32 (9th Cir. 2002). In that case, the court's refusal to require an adjudication of the likelihood of irreparable harm might be defended as appropriate deference to the views of an expert federal agency. Here, however, the district court rejected the expert agency's proposed stewardship measures and granted a blanket injunction that the agency believes is entirely unnecessary. As applied in this case, *Idaho Watersheds* stands broadly for the proposition that district courts may issue blanket injunctions in NEPA

cases without resolving genuine disputes over the likelihood of irreparable harm under more tailored prescriptions.

The Ninth Circuit's opinion is straightforward and unapologetic in its view that factual disputes as to irreparable harm are simply immaterial to the propriety of injunctions in NEPA cases, where an agency will consider those issues in preparing its EIS. The Ninth Circuit cited approvingly the district court's conclusion that there were no "material" factual disputes meriting an evidentiary hearing (Pet.App.17a)—despite the court of appeals' general adherence to the rule that "a district court must hold an evidentiary hearing ... unless ... the facts are undisputed," *id.*, its acknowledgement that "[t]he parties' experts disagreed over virtually every factual issue," Pet.App.9a, and its recognition that petitioners sought a hearing to "'assess the viability of [petitioners'] witnesses' opinions ... [and] resolve [petitioners'] disputes with plaintiffs' witnesses,'" Pet.App.16a-17a (citation omitted). The Ninth Circuit's square holding is thus that the factual disputes it acknowledged existed were legally "immaterial" under *Idaho Watersheds* because they overlapped with the issues the agency would be considering in its EIS. It ruled that examination of the likelihood of irreparable harm under appropriate stewardship measures was "more properly addressed by the agency in the preparation of an EIS." Pet.App.17a-18a. The Ninth Circuit thereby unmistakably set forth an *exception* to the traditional four-factor test for injunctive relief, rather than merely misapplying it, and there is no reason to doubt its determination to apply that exception in future cases.

Indeed, respondents and the government both *admit* that the Ninth Circuit applied a special rule here because APHIS's EIS process was ongoing. *See* Opp.28 (refusal to adjudicate issue was proper because "whole point of NEPA is to require the *agency* to resolve those issues *in the first instance* through the preparation of an EIS" (second emphasis added)); U.S. Br.9 (exception applied "because the injunction will be in effect only until APHIS completes an EIS"). Since additional agency analysis is virtually *always* part of the remedy for a NEPA violation, the Ninth Circuit's exception to the irreparable harm requirement threatens to apply in virtually all NEPA cases arising in that circuit. Judge Smith shrewdly noted as much. Pet.App.26a (Smith, J., dissenting) ("There aren't many environmental cases that don't fit into the majority's newly-created exemption."). There is accordingly no reason to allow further percolation as the government suggests. U.S. Br.13. Absent this Court's review, the only question is *how often*, not *whether*, the Ninth Circuit will refuse to apply the controlling law.

3. Respondents argue that certiorari is unwarranted because the lower courts' opinions can be read narrowly to hold merely that a hearing was unnecessary on these facts because "uncontested evidence" proved that cross-pollination had already occurred despite farmers' voluntary use of isolation distances "similar" to those proposed by APHIS. Opp.10; *accord* Opp.18 (stating district court's order "rested in large part" on that "fact"), 19-20, 27-28. The lower courts' reliance on *Idaho Watersheds* belies that fact-bound characterization. Indeed, in the follow-on sugarbeets litigation, respondents themselves advocate a far broader reading of the Ninth Circuit's decision here. *See* SJCMS at 7 (arguing that the "Ninth Circuit

has held repeatedly that an evidentiary hearing is not required before issuing an injunction")]]

A brief review of the record belies respondents' characterization and highlights the Ninth Circuit's fundamental departure from this Courts' precedents.

First, respondents' repeated insistence that cross-pollination has occurred with "equivalent" isolation distances does not make those claims "undisputed" or a "fact." As the court of appeals recognized, petitioners vehemently disputed respondents' anecdotal accounts of supposed "contamination," moved to strike respondents' evidence on hearsay grounds (which the district court never ruled upon), demonstrated that APHIS's proposed stewardship measures were in fact far more protective than the previous, voluntary measures, and sought an evidentiary hearing specifically to subject respondents' evidence to cross-examination. Pet.8-9, 31-33.

Second, respondents' emphasis on the "finding" that "contamination has occurred," Opp.2, 7-9, 18-19, illustrates just how far the Ninth Circuit has strayed from *Winter*. The district court's "finding" related only to *seed* crops, which constitute less than 1% of alfalfa acreage. *See* Pet.3. The district court *never* found that cross-pollination had or was likely to occur *from or to hay crops*, Pet.30-31, and even today respondents never meaningfully contest petitioners' evidence that the risk of hay-to-hay cross-pollination is roughly 2.5 in one million. *See* Pet.30. The blanket injunction affirmed by the Ninth Circuit is thus unsupported by *any* findings of likely irreparable harm for 99% of its breadth.

The injunction is grossly overbroad as to seed crops as well. APHIS proposed (and petitioners supported) increasing the customary isolation distances for those

crops from 900 feet to as much as three miles—a full 1660% increase (thoroughly belying respondents' repeated suggestion that the measures were "equivalent" or "substantially similar" to existing measures, Opp.8-9, 15, 18). Respondents conceded—as they concede now (Opp.9 n.6)—that a "five-mile isolation distance" or distances of "several miles" would be effective to prevent cross-pollination (a self-described "*zero* tolerance" approach) and thus *any* chance of irreparable harm. These three-mile and "five-mile"/"several miles" distances thus represented the endpoints of the spectrum of even *conceivably acceptable* injunctions. The district court was obligated to evaluate all available stewardship measures—including isolation distances—and narrowly tailor its injunction. But it rejected the use of isolation distances out of hand and instead enjoined *all* RRA planting—whether seed or hay—even on farms that are more than 100 miles from any conventional or organic alfalfa. Pet.App.108a. The court of appeals' affirmance of that decision is flatly inconsistent with this Court's holding in *Winter*.

Without benefit of *Winter*, moreover, the district court had employed the Ninth Circuit's then-controlling mere "possibility of irreparable harm" standard. *See* Pet.28-29. The district court expressly based its injunction on a finding of a mere "potential" for irreparable harm, *see* Pet.29; Pet.App.72a, 75a. But despite petitioners' invocation of *Winter*, the Ninth Circuit refused on rehearing to remand this case for application of the correct standard.

4. The government suggests that disputes over injunctive relief in APA cases like this may not warrant evidentiary hearings because the lawfulness of an agency's action is ordinarily judged based on the

administrative record and the agency should have the opportunity on remand to fashion appropriate relief. U.S. Br.16. The first point is a red herring and the second further highlights the necessity for certiorari.

Although the likelihood of success in an APA challenge is ordinarily adjudicated based solely on the administrative record, that issue had already been decided in respondents' favor on summary judgment and it was therefore no longer a matter of dispute at the remedies stage. Then, the parties' dispute focused on the likelihood of irreparable harm and the balance of harms under APHIS's proposed stewardship measures, issues that had never been litigated before the agency. In contrast to the district court's review of the merits of this NEPA case, its adjudication of the parties' dispute over the appropriate remedy could only be resolved by reference to materials outside of the administrative record. Petitioners and the government thus adduced substantial new evidence before the district court supporting the efficacy of APHIS's proposed stewardship measures. An evidentiary hearing to adjudicate those issues would have shown far *more* respect for the government's expert views than the district court's summary rejection of those views on a paper record.

After it rejected APHIS's proposed injunction, the district court then compounded its legal errors by flatly prohibiting the agency, in advance, from adopting any measured interim response during the pendency of the EIS process. *See* Pet.App.108a ("Before granting Monsanto's deregulation petition, even in part, the federal defendants shall prepare an [EIS]."). The court justified that extraordinary prohibition for the same erroneous reason that it refused to enforce the traditional prerequisites to injunctive relief—that

NEPA always requires an injunction to preserve the status quo until the EIS is complete. Pet.App.69a (rejecting less severe measures as a "cramped reading of this Court's Order and NEPA"), 75a. *But see Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 544-45 (1987) (reversing Ninth Circuit's "erroneous[] focus[] on the statutory procedure rather than on the underlying substantive policy").

5. Finally, contrary to respondents' and the government's assertions, the Ninth Circuit's decision in this case conflicts squarely with the decisions of other courts of appeals. To begin with, the government concedes that nearly every circuit has adopted a general rule requiring an evidentiary hearing to resolve genuine and material factual disputes. U.S. Br.14-15. And the government admits the parties here disputed the likelihood of irreparable harm under APHIS's proposed stewardship measures. U.S. Br.7-8, 11-12. The government says that the Ninth Circuit's refusal nonetheless to afford petitioners an evidentiary hearing is consistent with the precedents of those other circuits, but it does not even try to defend that position. U.S. Br.14-15.

As respondents recognize (at 3), the Ninth Circuit's reasoning is grounded in the "ephemeral nature" of NEPA-based injunctions. That approach is directly contrary to the categorical rule adopted by the D.C. Circuit in *Microsoft*, which excepts *only* temporary restraining orders, which generally last no more than *10 days*. *See* Pet.26-27. Neither respondents nor the government dispute either (1) that the vast majority of circuits follow *Microsoft*'s standard or (2) that *no other circuit* has ever adopted the Ninth Circuit's NEPA-based exception, despite their adjudication of hundreds of NEPA cases. Pet.26-28.

The Ninth Circuit's decision also conflicts squarely with the Second Circuit's decision in *Huntington v. Marsh*, 884 F.2d 648 (2d Cir. 1989), *cert. denied*, 494 U.S. 1004 (1990). *Huntington* rejects the notion that an agency's ongoing EIS process negates the need for an evidentiary hearing. Pet.21. Contrary to the government's suggestion (at 14 n.2), the Second Circuit not only held that the district court improperly "assumed irreparable harm," but also decided how that disputed issue must be adjudicated: it specifically remanded for an *evidentiary hearing*. 884 F.2d at 651, 653-54.

Respectfully submitted,

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DECEMBER 30, 2009

AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
NOV 2 3 2009
OFFICE OF THE CLERK

(4)

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to The United States Court of Appeals For the Ninth Circuit

BRIEF OF AMERICAN FARM BUREAU FEDERATION, BIOTECHNOLOGY INDUSTRY ORGANIZATION, AMERICAN SEED TRADE ASSOCIATION AND NATIONAL CORN GROWERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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BRIEF OF AMERICAN FARM BUREAU FEDERATION, BIOTECHNOLOGY INDUSTRY ORGANIZATION, AMERICAN SEED TRADE ASSOCIATION AND NATIONAL CORN GROWERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICI CURIAE*[1]

The American Farm Bureau Federation ("Farm Bureau") is a general farm organization representing over 6.2 million member families. Farm Bureau was established in 1919 to protect, promote and represent the business, economic, social and educational interests of American farmers and ranchers. Farm Bureau policy, which is developed through a member-controlled, grassroots process, supports the use of agricultural biotechnology, as well as conventional and organic farming.

The Biotechnology Industry Organization ("BIO"), created in 1993, is the world's largest biotechnology trade association. Its mission is to champion biotechnology on behalf of its 1,200 members—a wide range of entities that are involved in the research and development of numerous innovative biotechnologies. Through its Food and Agriculture Section, BIO has taken the lead in promoting the safety and benefits of genetically-engineered crops developed through agricultural biotechnology. BIO advocates for scientific regulatory approaches for these crops both domestically and abroad, while also supporting the concurrent cultivation of conventional and organic crops.

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[1] Pursuant to Supreme Court Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici* and their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Founded in 1883, the American Seed Trade Association ("ASTA") is a voluntary, nonprofit national trade association representing approximately 740 members involved in seed production and distribution, plant breeding, and related industries in North America. ASTA's mission is to enhance the development and movement of quality seed worldwide. Many ASTA members are research-intensive companies engaged in the discovery, development, and marketing of enhanced seed—*i.e.*, seed that has been modified to express certain beneficial or desirable traits.

Founded in 1957, the National Corn Growers Association ("NCGA") represents approximately 35,000 dues-paying corn growers and the interests of more than 300,000 farmers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state associations and checkoff organizations work together to help protect and advance corn growers' interests.

Farm Bureau, BIO, ASTA and NCGA support the continued application of advances in agricultural biotechnology like the Roundup Ready alfalfa seed at issue in the present case. Sustained progress in this field requires a firm commitment to science-based regulations and policies. When dealing with products like genetically-engineered crops that have undergone extensive field testing, decisions must be based on evidence, not anecdotes and speculation. Unfortunately, the lower courts in this instance decided to enjoin the use of Roundup Ready alfalfa without fulfilling their legal obligation to evaluate the relevant data.

SUMMARY OF ARGUMENT

The injunction in this case is a watershed event for American agriculture in general, and more specifically for agricultural biotechnology. Agricultural biotechnology is already adopted widely in the U.S. for a number of key crops—including corn, cotton, papaya, sugar beets and soy—

using a robust and established regulatory process. This Court's review is warranted not only because the courts below abandoned the well-established principle that evidence of likely irreparable harm is a prerequisite to issuance of an injunction, but also because ignoring the lack of such evidence raises especially important questions in the context of efforts by innovators to bring the benefits of genetically-engineered crops to market.

Roundup Ready alfalfa, like all genetically-engineered crops, is the product of extensive research and testing that take place over the course of many years. But the research and testing that go into developing these crops are just the beginning. Before a new genetically engineered crop is commercialized in the United States, it is subject to an extensive, science-based regulatory review and authorization process that will include up to three separate federal agencies—for food and feed crops, the U.S. Food and Drug Administration ("FDA"); in some other cases, the U.S. Environmental Protection Agency ("EPA"); and, most relevant in the circumstances of this case, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS" or the "Agency").

The federal regulatory system ensures the safety of genetically-engineered crops, opening the door to the incredible public benefits that those crops offer. For farmers, genetically-engineered crops mean lower input costs and higher yields, which translate into improved incomes. The same higher crop yields benefit consumers all over the world, where agricultural biotechnology offers hope for meeting the planet's rapidly growing demands for food, feed, fuel and fiber. Between 1996 and 2007, this additional production has contributed enough kilocalories of energy to feed about 402

million people for a year.[2] Genetically-engineered crops also allow farmers to control harmful weeds and pests using fewer, more environmentally friendly farming practices. Glyphosate, the herbicide used by Roundup Ready alfalfa farmers, is less toxic than common aspirin, and it quickly decomposes in the soil so that it has no residual activity or long-lasting environmental effects.[3] These and other biotechnologies make sustainable agriculture feasible in more places around the world.

In spite of these current and future benefits, and despite the fact that genetically-engineered crops are already safely consumed by millions of people around the globe, public understanding of agricultural biotechnology remains modest. U.S. Department of Agriculture statistics show, however, that the overwhelming majority of soybeans, cotton, and corn in the United States are biotech varieties. These crops are a firmly established part of the agricultural industry with broad applications offering widespread benefits. The district court in this case, instead of fashioning an injunction based on the evidence before it, declined to conduct an evidentiary hearing and applied a legal standard that effectively presumed the existence of irreparable harm. The court of appeals, in a two-to-one vote, sanctioned the lower court's approach. Without this Court's review, the present case could begin a wave of anti-biotechnology injunctions with the potential to generate uncertainty not only in the agricultural biotechnology indus-

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[2] Graham Brookes, Peter Barfoot, *Focus on income, well-being and food security, Biotech crops: evidence, outcomes and impacts 1996-2007*, PG Economics, Ltd, October 2009, available at http://www.pgeconomics.co.uk/pdf/focusonincomeeffects2009.pdf

[3] Glyphosate Pesticide Information Profile, Extension Toxicology Network, Cornell University, Cooperative Extension, available at http://pmep.cce.cornell.edu/profiles/extoxnet/dienochlor-glyphosate/glyphosate-ext.html.

try, but also throughout American agriculture and in the global food market.

ARGUMENT

I. Scientifically-Regulated Agricultural Biotechnology Is Safe And Beneficial.

The first commercial plantings of genetically-engineered crops occurred in 1996. By 2008, 13 million farmers planted more than 309 million acres in 25 different countries. *See* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2008* (Feb. 2009).[4] The development and delivery of benefits from agricultural biotechnology into the commercial marketplace have been incredible, with the U.S. Department of Agriculture indicating that 91% of soybeans, 88% of cotton, and 85% of corn in the United States are biotech varieties. Two factors explain this rapid adoption of agricultural biotechnology. First, the United States has led the way in establishing a science-based regulatory process that allows innovators to bring safe, new products to market. Second, genetically-engineered crops work. They work to increase incomes for farmers, they work to provide more and better food for consumers and they work to lessen the impact of agriculture on the environment. In short, agricultural biotechnology currently provides significant benefits to many commodity crops, while also helping to offer solutions to help feed, fuel and heal the world in the future.

A. Genetically-engineered crops are subject to science-based federal regulation.

Since 1986, the federal government has regulated agricultural biotechnology crops under a "Coordinated Framework for Regulation of Biotechnology." *See* 51 Fed. Reg. 23302 (June 26, 1986). Three different agencies—APHIS,

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[4] *See* http://croplife.intraspin.com/Biotech/papers/ID_372_james .pdf.

EPA and FDA—share responsibility for regulatory review of genetically engineered plants. APHIS, the agency involved in the present lawsuit, regulates plant products of biotechnology as potential plant pests until, based on a review of an extensive scientific database, including the results of APHIS-regulated field trials, the Agency makes a determination that the genetically engineered plant does not pose a plant risk. FDA thoroughly reviews the safety profile of genetically engineered food crops and enforces rigorous safety standards for food and feed derived from these crops. Some types of genetically engineered plants have been developed to produce their own pesticides. EPA registers the sale and distribution of these plant incorporated protectants. Under this system, each agency regulates products to the extent they fall within the sphere of that agency's authority. Consequently, multiple agencies may regulate different aspects of the same crop.

This coordinated federal effort makes genetically-engineered crops among the most thoroughly tested and stringently regulated in history. The regulatory system is science-based, meaning that agency decisions depend on the results of controlled testing of these products. As a result, the agricultural biotechnology products that have been commercialized under the U.S. regulatory system have been shown to be as safe for producers, consumers and the environment as their conventional counterparts.

B. Genetically-engineered crops create important benefits for producers, consumers and the environment.

Beyond this demonstration of safety, genetically-engineered crops improve the circumstances of farmers, consumers and the environment. The advantages of Roundup Ready alfalfa illustrate these wide-ranging benefits. Alfalfa is a 22-million acre per year crop in the United States. Nearly all of this alfalfa is harvested for animal feed. Unlike con-

ventional alfalfa, Roundup Ready alfalfa is genetically engineered to survive the application of glyphosate, the active ingredient in the herbicide commercially known as Roundup. So a farmer who plants Roundup Ready alfalfa can use glyphosate to control weeds, in lieu of a more expensive combination of other herbicides. By producing more alfalfa while spending less on chemicals for weed control, the Roundup Ready alfalfa farmer can realize greater profits. Not surprisingly, alfalfa farmers were rapidly adopting the Roundup Ready variety when the district court issued its injunction in this case.

Livestock farmers—the primary purchasers of alfalfa hay—also benefit from the adoption of genetically-engineered Roundup Ready alfalfa. The presence of weeds reduces the nutritional value of alfalfa hay. When farmers plant Roundup Ready alfalfa, it increases both the quantity and quality of alfalfa hay available for purchase. In other words, Roundup Ready alfalfa allows the production of more hay with fewer weeds—exactly what alfalfa hay consumers want.

In addition to the benefits enjoyed by farmers and consumers, genetically-engineered crops like Roundup Ready alfalfa can help provide significant benefits for the environment. As already mentioned, farmers who plant Roundup Ready alfalfa can control weeds with glyphosate, as opposed to a variety of other herbicides. These alternatives to glyphosate may have greater impacts on the environment.

The multiple benefits of Roundup Ready alfalfa are just a few examples of agricultural biotechnology's potential to help feed the world. A 2004 study by the National Center for Food and Agricultural Policy showed that genetically-engineered crops increased yields by more than 5 billion pounds annually, and farm incomes by $2 billion. Sujatha Sankula, Edward Blumenthal, *Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2003 – An Update*

of Eleven Case Studies at 92 (Oct. 2004).[5] Globally, pesticide applications fell 6 percent between 1996 and 2004, due in part to the development of pest-resistant biotechnology in plants. Graham Brookes, Peter Barfoot, *GM Crops: The Global Economic and Environmental Impact — The First Nine Years 1996-2004* at 193, PG Economics, Ltd., AgBioForum 8 (2005).[6] Herbicide-resistant crops have both reduced the application of weed-controlling chemicals and facilitated the increased adoption of "no-till" farming methods that improve soil health and reduce erosion.

Astounding as these advances are, they amount to no more than a glimpse of what is possible. Agricultural biotechnology offers the world a way to help feed its population through safe, sustainable farming techniques that could raise the standard of living in rural communities throughout the world. This technology, and the crops derived from this technology, provide solutions to help feed, fuel and heal the world.

II. The Lower Courts' Approval Of An Injunction Without Scientific Evidence Of Harm Threatens The Agricultural Biotechnology Industry.

The legal principles governing the issuance of injunctive relief require courts to consider the relevant evidence of harm. *See Winter v. Natural Res. Def. Council*, 129 S.Ct. 365, 374-75 (2008). In the case of genetically-engineered crops like Roundup Ready alfalfa, that means a consideration of scientific evidence regarding the likelihood that the crop will cause the irreparable injury necessary to justify the "extraordinary remedy" of an injunction (*id.* at 376-77). The lower courts' failure to address the readily-available scientific evidence in this case is indicative of a larger problem en-

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[5] *See* http://www.ncfap.org/documents/2004finalreport.pdf.

[6] *See* http://www.pgeconomics.co.uk/pdf/v8n23a15-brookes.pdf.

demic to judicial handling of biotechnology: Products are so thoroughly studied and tested before being commercialized that courts must deal with substantial scientific evidence when considering possible injunctive relief. The lower courts' mishandling of that problem demands this Court's immediate review.

A. Scientific evidence is the only meaningful way to determine the likelihood of irreparable harm from a genetically-engineered crop.

This Court repeatedly has held that injunctive relief requires proof that the plaintiff is likely to suffer irreparable harm in the absence of an injunction, that such harm outweighs any harm the requested injunction is likely to cause, and that the injunction would be in the public interest. *See eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). The question here is how this standard should be applied in a case where plaintiffs seek to enjoin the use of agricultural biotechnology.

The district court had before it substantial scientific evidence addressing the likelihood that the continued use of Roundup Ready alfalfa would ***not*** irreparably harm the plaintiffs. Even if it were assumed true that normal levels of crop-to-crop pollen flow could cause irreparable harm—a conclusion not supported by science—a number of field studies have measured the gene flow between Roundup Ready alfalfa and conventional alfalfa using various "isolation distances" between plantings.[7] These studies, which were conducted under worst-case scenario conditions that allowed for more gene flow than would occur in the real world, demon-

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[7] To maintain the status quo while it conducted the environmental review ordered by the district court, APHIS proposed certain "stewardship measures," including minimum isolation distances between plantings, that were designed to prevent Roundup Ready alfalfa from coming into contact with conventional and organic alfalfa.

strate that the risk of cross-pollination feared by the plaintiffs is negligible. *See, e.g.*, Pet. App. 228a-29a. In particular, the studies showed that gene flow was less than 0.1% for alfalfa being grown for seed, and approximately 2.5 in a million (0.00025%) for alfalfa being grown for hay. *See, e.g.*, Pet. App. 168a-83a, 280a-81a. The studies presented to the district court also ruled out any realistic possibility that glyphosate-resistant weeds would develop during the period of the injunction.

The district court did not evaluate the scientific evidence it received within the framework of this Court's standard for issuance of injunctive relief. Faced with scientific studies directly relevant to the likelihood of irreparable harm, and evidentiary challenges to the plaintiffs' anecdotal claims of injury, the district court refused to conduct an evidentiary hearing. According to the Court of Appeals, this decision to eschew a hearing was an effort "to avoid the catch-22 situation" in which the district court would "perform the same type of extensive inquiry into environmental effects" that it had ordered APHIS to perform. Pet. App. 18a. In fact, the review of potentially significant environmental impacts required by the National Environmental Policy Act ("NEPA") is readily segregable from the question of likely irreparable harm necessitating immediate injunctive relief. Significant environmental impacts under NEPA do not necessarily qualify as "irreparable harm," and can often be completely mitigated in the normal course. The harm needed to invoke a court's injunctive powers, on the other hand, must be irremediable apart from an injunction. By blurring the line between these two distinct inquiries, the district court effectively enjoined the use of Roundup Ready alfalfa without appropriately considering the scientific evidence. As discussed, that evidence demonstrates the extreme improbability and practical impossibility of any measurable impact—let alone irreparable harm—occurring in the absence of an injunction.

The district court's refusal to hold an evidentiary hearing—endorsed over a dissenting opinion by the court of appeals—is precisely the wrong way to approach a question involving the potential impacts of genetically engineered crops. The potential for the incidence of the impacts alleged by the plaintiffs is scientifically measurable. The science submitted to the district court proved that the likelihood of harm under APHIS's proposed conditions was remote. Anecdotal accounts of "contamination" and hypothetical doomsday forecasts have no place in the injunction calculus when appropriately controlled scientific studies can provide data that allows for confident prediction. Ignoring this data is tantamount to an improper presumption of irreparable harm. *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 544-45 (1987). Worse, it allows mere speculation to trump carefully conducted scientific testing. The upshot is an injunction that flies in the face of this Court's rule requiring proof of likely irreparable harm (*see Winter*, 129 S. Ct. at 375), disrupting unnecessarily and generating uncertainty throughout the agricultural biotechnology industry.

B. Organic, conventional and Roundup Ready alfalfa farmers can and should coexist.

In addition to ignoring the scientific evidence regarding the effects of genetically-engineered crops, the lower courts' rulings in this case imagine a tension that need not exist between those farmers who employ agricultural biotechnology and those who do not. Both courts discounted APHIS's ability to enforce its proposed "stewardship requirements" for Roundup Ready alfalfa, without considering at all the ability of farmers to voluntarily comply with these protective measures. The "either-or" mentality reflected in the lower courts' opinions is another product of poor information, or a poor assessment of the available information, related to agricultural biotechnology and the farmers who employ it.

The coexistence of crops that should not be commingled is not a novel concept. Field corn and popcorn, for example, are grown in the same geographic regions, even though each variety has unique genetic traits that would harm the other's economic value if gene flow were to occur. Field corn and popcorn farmers accordingly employ management techniques that have long allowed them to peacefully coexist. The same sorts of techniques, including the types of stewardship requirements proposed by APHIS in this case, have also allowed conventional, organic and genetically-engineered crops to coexist. Studies confirm that such coexistence need not cause economic or commercial hardship for farmers. *See, e.g.*, Graham Brookes, Peter Barfoot, *Co-Existence in North American agriculture: can GM crops be grown with conventional and organic crops?* (June 2004).[8]

Farm Bureau, BIO, ASTA and NCGA—organizations whose rank-and-file members are intensely interested in the issue—strongly support the coexistence of conventional, organic and genetically-engineered crops. By questioning the effectiveness of management practices, and APHIS's ability to enforce them, the lower courts in this case are unjustifiably casting doubt on the basic concept of coexistence. The courts' skepticism apparently arose not from any evidence that APHIS's proposed stewardship measures would prove ineffective, but from an unwarranted apprehension that agricultural biotechnology cannot coexist with conventional or organic farming methods. A decision stemming from this kind of unsupported assumption does not and cannot satisfy the well-established standards for issuing an injunction.

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[8] *See* http://croplife.intraspin.com/Biotech/papers/152Coexistence report-NAmericafinalJune2004.pdf.

C. The injunction issued in this case could mark a departure from scientific review of agricultural biotechnology.

Experience has shown that in spite of its numerous, proven benefits and track record for safety, agricultural biotechnology is not well understood by the public at large. In Europe, the frightening concept of the inappropriately named "Frankenfood" continues to color public opinion even though the organization that did the most to promote the term stopped using it years ago. *See* Paul Voosen, *Ghost of 'Frankenfood' Haunts Europe*, Greenwire (Oct. 21, 2009).[9] This has helped lead to a majority of survey respondents in Europe remaining opposed to agricultural biotechnology. *See id.* Six European countries have effectively banned genetically-engineered crops. *See id.* Despite consistent findings of safety from a variety of European scientific bodies, the European Union has not approved a genetically-engineered crop for growing since 1998.

By approving an injunction without considering the relevant scientific evidence, the lower courts in this case may be setting agricultural biotechnology in the United States on a similar path. Already, another judge in the Northern District of California has ruled that APHIS's environmental review of genetically-engineered sugar beets is insufficient. *See Center for Food Safety v. Vilsack*, No. 08-cv-00484, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009). That court now faces the same sort of injunction decision that is the subject of the present petition. The prime difference is that 95% of sugar beet farmers have already switched to the genetically-engineered variety, which was commercialized four years ago. An injunction like the one issued against the use of Roundup Ready alfalfa accordingly would cause a massive

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[9] *See* http://www.nytimes.com/gwire/2009/10/21/21greenwire-ghost-of-frankenfood-haunts-europe-55309.html

disruption for the overwhelming majority of sugar beet farmers, sugar processors and the communities in which they reside.

The ripple effect of the injunction in this case could spread far beyond genetically-engineered sugar beets. APHIS already has deregulated several other genetically-engineered crops, including varieties of corn, cotton, papaya, sugar beets and soy. But dozens of other products are currently going through the regulatory field testing process. Decisions like the injunction against Roundup Ready alfalfa dramatically increase the degree of uncertainty surrounding the availability of these genetically-engineered crops. Seed producers will be delayed in seeing financial break-even on their products that have been reviewed by federal agencies and determined to be safe. Farmers who spent large amounts of time and money preparing to grow Roundup Ready alfalfa now have no idea when they might see a return on their investment. Sugar beet farmers are standing on the same precipice, not knowing whether they will face an injunction that could prevent them from even planting, much less selling their crops.

The ongoing experience in Europe—more than a decade with little progress for genetically-engineered crops—shows that for an industry as young as agricultural biotechnology, the potential for setbacks is real. The United States has put in place a regulatory regime that has been effectively testing and approving genetically-engineered crops, allowing farmers and consumers in this country to reap the amazing benefits that those crops offer. Now the U.S. legal system has thrown sand in the gears, rejecting scientific evidence and creating industry-wide uncertainty. Especially in the context of a science-based industry like agricultural biotechnology, this refusal to consider objective data represents an important and deeply troubling departure from the established frame-

work for issuing injunctive relief that necessitates this Court's review.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted.

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NOVEMBER 2009

AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
NOV 23 2009
OFFICE OF THE CLERK

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO COMPANY, *et al.*,

Petitioners,

v.

GEERTSON SEED FARMS, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICUS CURIAE* PHYTAGRO, LLC IN SUPPORT OF PETITIONERS

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I. INTEREST OF AMICUS CURIAE[1]

San Diego based *Amicus Curiae* PhytaGro, LLC ("PhytaGro") is an early stage agbiotech company developing novel technologies that improve the productivity and quality of alfalfa.

With the growth of bio-fuels and the demand for protein from emerging nations, in recent years grain prices have reached unprecedented levels, creating pressure on the meat and dairy industry. In the United States, the increased conversion of farms into pasture based systems is evident and requires improved varieties of forage based feeds. PhytaGro sees this as a significant opportunity for its first two product lines: (i) a glyphosate resistant alfalfa and (ii) a high metabolisable energy (ME) alfalfa. These products will improve the productivity and nutritional value of alfalfa beyond that of conventional varieties.

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1. Pursuant to this Court's Rule 37.6, *amicus curiae* PhytaGro affirms that no counsel for any party has authored this brief in whole or in part, that no such counsel or party made a monetary contribution to fund the preparation or submission of this brief, and that no person other than *amicus curiae* and its counsel made such a monetary contribution. Pursuant to this Court's Rule 37.2, counsel of record for both Petitioners and Respondent were notified of the intent to file this brief at least ten days prior to the filing of this brief, and the parties' letters consenting to the filing of this brief have been filed with the Clerk's office.

PhytaGro is a competitor of Petitioner Monsanto Co. ("Monsanto"). Like Monsanto, one of PhytaGro's products under development will also render alfalfa plants resistant to glyphosate, or Roundup, as it is commonly known. Although the underlying technology is different from Monsanto's, plants from both companies will contain genes which perform the same essential function, detoxifying Roundup.

Accordingly, PhytaGro has a keen interest in this case; the lower court's injunction is a significant negative impediment for PhytaGro, a small emerging technology company seeking to bring further innovation to a major agricultural crop with significant implications for the animal feed business.[2] Notwithstanding the established safety and efficacy record of genetically modified ("GM") corn, canola, cotton, sugar beets and soybeans (which are all sold in the United States and elsewhere with glyphosate resistance), the release of GM alfalfa has been unreasonably delayed to the detriment of the United States farmer and those who have invested in the development of the technology to make the alfalfa industry more productive and sustaining. For this and the reasons discussed below, PhytaGro supports Monsanto Co., et al.'s Petition for Certiorari.

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2. PhytaGro's underlying technology is not sourced from Monsanto yet it will also confer Roundup resistance on alfalfa plants by detoxifying glyphosate.

II. SUMMARY OF ARGUMENT

A. Background of RR Alfalfa

This case involves a variety of alfalfa created to address the problems caused by weeds in alfalfa fields. Pet.App.126a-127a, 133a-134a. The alfalfa variety at issue has been genetically engineered to be resistant to Roundup, a broad-spectrum agricultural herbicide that controls nearly every type of weed in alfalfa crops. Pet.App.127a.[3] This alfalfa variety is known as Roundup Ready alfalfa ("RR alfalfa"). Because RR alfalfa is not harmed by Roundup, a farmer can use Roundup or a similar composition herbicide and eliminate weeds in their fields without harming the alfalfa. Pet.App.127a, 133a-134a.

Alfalfa stands are particularly prone to weed infestation. The ability to control weeds in alfalfa stands increases alfalfa productivity exponentially by removing weeds which typically compete with emerging alfalfa plants (thus also removing the need to overseed), increasing production and keeping stands clean over longer periods. Moreover, with RR alfalfa, the stand is more drought tolerant, farmers use fewer herbicides and generally lower their input costs of production. *See* Pet.App.121a-122a, 135a-136a, 239a.[4] The following chart shows the marked increase in alfalfa productivity for stands of RR Alfalfa as compared to stands of conventional alfalfa.

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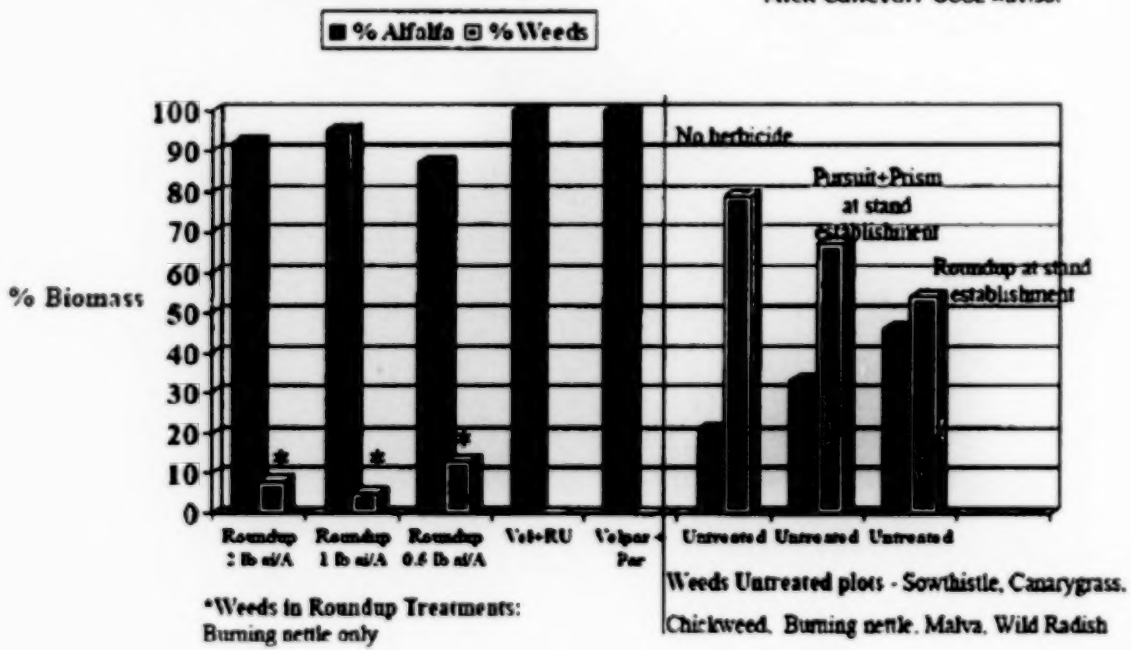
3. Roundup's active ingredient is glyphosate, which the Environmental Protection Agency ("EPA") has found to be one of the most environmentally responsible herbicides available commercially. Pet.App.195a-205a. The gene for glyphosate resistance occurs naturally, but not in alfalfa. Pet.App.43a.

4. Monsanto charges a technology fee that equates to $20/acre/annum. In the industry, farmers typically realize 2/3 of the value while paying 1/3 in fees. Therefore, the benefits of having RR alfalfa is estimated to be above $40/acre/annum.

Roundup Ready Alfalfa Trial
Dormant Herbicide Treatments Harvest
San Joaquin County 2003

Mick Canevari UCCE Advisor



This case is not about an insignificant crop used for just "hay." On the contrary, alfalfa is the fourth largest crop in the United States. *See* Sara Brown, *Alfalfa Takes a Stand*, The Farm Journal, December 11, 2007. Alfalfa is known as the "Queen of Forages" because it plays a critical role in feeding important livestock industries, particularly dairy and beef production. Globally, the world is experiencing a surge in demand for protein, driven by emerging third world economies which demand more protein as part of their diet instead of traditional carbohydrate-based diets. Increased United States exports of poultry, beef, pork and dairy are a consequence of this demand.

The alfalfa farmer also plays a role by providing a higher value feed for United States dairy and beef production, as well as for similar industries in countries which buy United States exports of alfalfa; for example, Canada, Mexico, Japan, Korea and Japan.[5] Notably, these markets have approved the importation of RR alfalfa from the United States. Access to high quality alfalfa is critical if these industries are to meet this demand and remain competitive. Increasing productivity in alfalfa production through technologies like Roundup resistance is a critical element of this effort.[6] In sum, RR alfalfa is a key

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5. Truth About Trade & Technology, *RR Alfalfa No Threat to Organic, Export Markets* (visited Nov. 22, 2009) <http://www.truthabouttrade.org/news/latest-news/9773-rr-alfalfa-no-threat-to-organic-export-markets>.

6. In time, other GM traits, being developed and implement in other crops will also become available in alfalfa production—for example, drought tolerance, salt tolerance, heat tolerance, nitrogen efficiency and so on. PhytaGro's high energy trait is another example of this trend.

agricultural crop and an important cog in the effort to feed the world's growing population and demand for higher quality food.

B. The Error in This Case

After regulating and monitoring the release of RR crops (corn, cotton, soybeans, canola, sugar beet) since the mid 1990s, the United States Department of Agriculture ("USDA") determined it was time to allow the production of RR alfalfa. Given the Government's considerable prior experience with other RR crops, the government determined an Environmental Impact Statement ("EIS") was not necessary in deciding to approve the sale of RR alfalfa. The government's documented experience with RR technology in other crops has established the safety and efficacy of the technology. (Moreover, if the rapid adoption of other RR crops by farmers is any gauge, alfalfa farmers would also embrace the technology.[7])

Plaintiffs, however, brought suit and sought an injunction against the government's deregulation of RR alfalfa. Plaintiffs alleged irreparable harm from the chance that GM alfalfa would cross-pollinate with organic alfalfa in other fields. In response, the government proposed measures that would virtually

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7. ISAAA Briefs, Brief 36: *GM Crops: The First Ten Years - Global Socio-Economic and Environmental Impacts* (visited Nov. 21, 2009) <http://www.isaaa.org/Resources/Publications/briefs/36/download/isaaa-brief-36-2006.pdf>.

eliminate any chance for cross-pollination with non-GM alfalfa.[8]

In granting the Permanent Injunction Order below, the district court stated injunctive relief should issue "in the run of the mill NEPA [National Environmental Policy Act of 1969 (42 U.S.C. § 4332(C))] case" and that "more liberal standards for granting an injunction" apply in NEPA cases. Pet.App.55a, 65a-66a (citations omitted). Notably, the district court never made the requisite finding—nor did it even conduct an full evidentiary hearing—to determine that irreparable harm was likely, especially with the government's proposed mitigation measures against cross-pollination in place. Pet.App.60a-79a.

The Ninth Circuit affirmed. The Ninth Circuit upheld the district court's nationwide injunction against planting any genetically modified ("GM") alfalfa until the time the government prepared an EIS. It affirmed the injunction despite the absence of a finding that the injunction was necessary to prevent the alleged irreparable harm of possible cross-pollination. Rather, the Ninth Circuit punted the issue and concluded those "disputed matters [were] issues more properly addressed by the agency in the preparation of an EIS." Pet.App.95a-96a (citing *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 831 (9th Cir. 2002)).

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8. Experts below explained that, with the government's proposed interim measures in place, the possibility of cross-pollination among hay crops—which account for 99 percent of alfalfa acreage—would be "negligible." The risk was estimated at approximately 2.5 in one million (0.00025 percent). Pet.App.160a, 229a-235a, 280a-281a, 378-380a.

This Court then issued its decision in *Winter v. NRDC*, 129 S.Ct. 365 (2008). *Winter* confirmed a plaintiff bringing a NEPA action must establish they are likely to be irreparably harmed before a court can order injunctive relief. *Id.* at 374-375. Monsanto sought rehearing, based on the *Winter* decision and other grounds. The Ninth Circuit issued an amended opinion, but denied rehearing. Pet.App.107a. The amended opinion does not discuss the *Winter*'s rule that a finding of irreparable harm must exist before injunctive relief may be granted for a NEPA violation. The amended opinion merely adds citations to *Winter* in its unchanged decision.

Two and one-half years have passed since the initial injunction order. There is no EIS and the injunction continues.

As discussed more fully below, the Ninth Circuit erred in endorsing a rule that there is a presumption of harm in environmental cases. The Ninth Circuit effectively and wrongly relied on this presumption as an excuse not to require a finding of irreparable harm. This is an erroneous presumption which stems from a misunderstanding of GM agriculture, its governmental oversight, and the practical ramifications of an injunction that dramatically limits our nation's ability to produce an important food source. Moreover, its ruling gives no regard to the USDA's considerable positive prior experience with RR technology, now implemented in literally millions of acres of other GM crops grown annually in the United States and elsewhere.

III. ARGUMENT

A. The Ninth Circuit Improperly Endorses a Presumption of Irreparable Harm For Injunctions in Environmental NEPCO Cases.

1. The Presumption of Irreparable Harm Has Been Rejected By This Court.

The Ninth Circuit decision here effectively resurrects the presumption of irreparable harm in environmental cases that this Court repudiated explicitly in *Amoco Prod. Co. v. Vill. of Gambell*, 470 U.S. 531, 542-545 (1987) (reversing Ninth Circuit presumption of irreparable harm in environmental cases) and implicitly in *Winter, supra*, 129 S.Ct. at 376.

In *Winter v. NRDC*, this Court confirmed a plaintiff bringing a NEPA action must establish they are likely to be irreparably harmed before a court can order injunctive relief. *Id.* at 374-375. This Court stated the traditional four factor injunction test applies no differently to injunctions sought in the NEPA context pending the government's preparation of an EIS than in other situations. *Winter, supra*, 129 S.Ct. at 374-376. The Ninth Circuit decision here shows it persists in its view that NEPA plaintiffs are exempt from that requirement.

Here, the Ninth Circuit affirmed the district court's conclusion that a court need not decide the likelihood of irreparable harm because this would be done by the government in preparing an EIS. This is circular. There can be no injunction pending on EIS unless there is *first*

a finding of irreparable harm. The Ninth Circuit now excuses any court from finding irreparable harm before issuing an injunction pending an EIS in a NEPA case.[9] This is error as a matter of law and, as discussed below, such injunctions impose great costs on farmers, science and, ultimately, all consumers.

2. The Presumption of Irreparable Harm Improperly Stems From an Erroneous Understanding of GM Alfalfa That Ignores the Well-Established Safety and Efficacy of RR Technology.

a. GM Plants Have Long Been Approved As Safe and Are Recognized As Crucial to Producing Adequate Food for All the World's People.

Since the mid 1990s, GM crops have been approved for sale by the United States government and broadly adopted by farmers in the United States and in over 30 other countries.[10] In 2008, over 62.5 million hectares of

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9. Other recent Ninth Circuit decisions refuse to apply *Winter*'s holding. *See, e.g.*, *Nelson v. NASA*, 568 F.3d 1028, 1050 (9th Cir. 2009) (Kleinfeld, J., dissenting) ("The panel's injunction failed to consider this public interest factor, contrary to the Supreme Court's recent admonition [in *Winter*]."); *Greater Yellowstone Coal. v. Timchak*, 323 Fed. Appx. 512-515 & n.1 (9th Cir. 2009) (despite *Winter*, granting temporary stay of activity because of "possibility that the district court may conclude on remand that irreparable harm *might* occur" (emphasis added).

10. ISAAA Briefs, Brief 36: *GM Crops: The First Ten Years - Global Socio-Economic and Environmental Impacts* (visited Nov. 21, 2009) <http://www.isaaa.org/Resources/Publications/briefs/36/download/isaaa-brief-36-2006.pdf>.

GM crops were cultivated in the United States and over 125 million were cultivated worldwide.[11] This exuberant adoption of GM crops has occurred because of the undeniable safety record of these crops and the tremendous increases in productivity they afford to farmers. The RR trait that Monsanto and PhytaGro seek to bring to the 22 million acre United States alfalfa market has been well tested, is demonstrably safe and efficacious, and has been demonstrated to be so by the United States government.

b. Specifically, GM Alfalfa Is Safe and Boosts Food Production Exponentially.

In the last 13 years, the United States and many international markets have seen the prevalent adoption of RR canola, corn, cotton, soybeans and now sugar beets (the so-called "major GM crops"). In fact, 85 percent of corn grown for animal feed in the United States is RR corn. Similarly, 68 percent of United States soybean production, mostly used for animal feed and bio-fuels production, is RR.[12] In addition, scientists all over the globe are adapting the RR technology to other

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11. ISAAA Brief 39-2008: Executive Summary: *Global Status of Commercialized Biotech/GM Crops: 2008, The First Thirteen Years, 1996 to 2008* (visited Nov. 20, 2009) <http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html>.

12. The Free Library by Farlex, *Biotech Soybeans Benefit Environment (Ag Earth Stewards)* (visited Nov. 22, 2009) <http://www.thefreelibrary.com/Biotech+soybeans+benefit+environment.+(Ag+Earth+Stewards).-a084052888>.

crops[13]—lupins/lupines,[14] wheat,[15] and more. Moreover, new GM traits are being developed; for example, papayas that are resistant to devastating viruses.[16] New traits in sugar cane, a major source of bio-fuels, is another crop that is undergoing major GM development.[17] To deal with climate change, GM traits like nitrogen efficiency, drought tolerance, heat tolerance and salt tolerance are under development.[18] There are many other examples.[19]

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13. Wikipedia, *Genetically Modified Food* (visited Nov. 22, 2009) <http://en.wikipedia.org/wiki/Genetically_modified_food#Development>.

14. Evergreen Farm Weekly, *New Herbicide-Resistant Lupin on the Way* (visited Nov. 22, 2009) <http://www.evergreen.asn.au/files/documents/EvergreenFarmWeeklyPage12Mar09page20condensed.pdf>.

15. Food Navigator.com, *Syngenta Moves Closer to Launching GM Wheat* (visited Nov. 22, 2009) <http://www.foodnavigator.com/Financial-Industry/Syngenta-moves-closer-to-launching-GM-wheat>.

16. GMO Compass, *Papayas* (visited Nov. 22, 2009) <http://www.gmo-compass.org/eng/grocery_shopping/fruit_vegetables/14.genetically_modified_papayas_virus_resistance.html>.

17. Checkbiotech, *GM sugarcane trials in Brazil, Australia* (visited Nov. 22, 2009) <http://greenbio.checkbiotech.org/news/gm_sugarcane_trials_brazil_australia>.

18. ISAAA Brief 39-2008: Executive Summary, *Global Status of Commercialized Biotech/GM Crops: 2008, The First Thirteen Years, 1996 to 2008* (visited Nov. 20, 2009) <http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html>.

19. Peggy G. Lemaux, *Biotechnology 101: Some of What You Need to Know in a Few Minutes* (visited Nov. 22, 2009) <http://alfalfa.ucdavis.edu/+producing/files/20041215_Lemaux.pdf>.

The 13 year safety and efficacy track record with major GM crops is undeniable. A huge body of favorable scientific evidence supports its safety record, as well as the significant productivity gains enjoyed by farmers of the major GM crops. The important benefits of RR alfalfa and other GM crops are proved by their undisputed increased productivity, higher economic returns, higher quality products, and significant environmental benefits through lower input costs, i.e. lower costs of labor, chemicals, petroleum to run farm equipment *etc.* The simple truth of these benefits is proved by the adoption rates of GM crops in the United States and elsewhere. In 2008, the global acreage of biotech crops grew by 9.4 percent or 10.7 million hectares.[20] Farmers, being the ultimate stewards of the land and determinates of productivity, have adopted the major GM crops *en mass* wherever they are introduced.

The alfalfa industry simply seeks to utilize the same technology for RR crops that has been found safe and has brought huge benefits to other agricultural markets. It is undisputed that RR alfalfa is safe for food and animal feed. Pet.App.43a. RR alfalfa is otherwise identical to conventional alfalfa. *Id.* The evidence also shows a similar pattern of safety, productivity, and economic benefits resulting from RR alfalfa as from other GM plants. Alfalfa is particularly suited to the adoption of GM traits in general, and the RR trait in particular, because alfalfa stands are particularly

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20. ISAAA Brief 39-2008: Executive Summary, *Global Status of Commercialized Biotech/GM Crops: 2008, The First Thirteen Years, 1996 to 2008* (visited Nov. 20, 2009) <http://www.isaaa.org/resources/publications/briefs/39/executivesummary/default.html>.

susceptible to weed infestation. If this can be addressed, farmers can expect significant increases in productivity.[21]

However, without a full evidentiary hearing on the issue of irreparable harm from alleged RR alfalfa cross-pollination, this body of evidence was not adequately considered. Without an actual fact-based hearing on potential harm, Plaintiffs below were able to conjure unfounded fear toward RR alfalfa that lead to an erroneous presumption of irreparable harm from deregulation. As discussed, *supra*, before granting an injunction, a court must assess the facts and determine the risk of irreparable harm. If this had been done, the record shows a long scientific track record of RR technology that is safe and extremely beneficial to society. Confirming the rule that an actual factual hearing must occur and there can be no presumption of harm is all the more important in GM cases where fear of science or the unknown can lead to injunctions based on that unfounded apprehension alone.

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21. Productivity in this context means getting greater production with fewer inputs or resources. The chart, *supra*, demonstrates the difference in production between RR and non RR stands of alfalfa. *See also generally* University of California Alfalfa & Forages, *Producing Alfalfa: Biotechnology and Roundup Ready Alfalfa* (visited Nov. 22, 2009) <http://alfalfa.ucdavis.edu/+producing/index.aspx?cat=Biotechnology and Roundup Ready Alfalfa>.

3. The Regulatory Structure for GM Products Makes the Presumption of Irreparable Harm Doubly Erroneous.

The United States has been the leader in the development and adoption of GM crops. The USDA, through the Animal and Plant Health Inspection Service ("APHIS"), has been the United States agency charged with the evaluation and deregulation of GM crops for approximately 15 years in conjunction with other government agencies, including the United States Environmental Protection Agency ("EPA") and the United States Food and Drug Administration ("FDA").

APHIS, accordingly, has a huge reservoir of experience and knowledge of GM crops and, specifically, GM alfalfa. After years of monitoring and research—and with literally billions of meals safely consumed from GM crops—APHIS concluded RR alfalfa should be deregulated. On mere suppositions of harm and without a factual hearing, the court below ordered the USDA to "do over" its own process of determining RR alfalfa should be deregulated. It also enjoined (for what has now been several years) all use of RR alfalfa in the meantime. The lower court compounded this error by ignoring APHIS' proposed stewardship conditions which would have readily addressed Plaintiffs' concerns about "irreparable injury" from any alleged chance of cross-pollination.

The Ninth Circuit decision affirming the district court second guesses the government and will cost taxpayers millions of dollars in unnecessary and duplicative research and analysis. Moreover, this injunction—in place since early 2007—has led to millions of dollars in lost economic benefits to farmers and lost productivity of food, which, in turn, affects all Americans and even the world. The Ninth Circuit ignored the USDA and its considerable knowledge and experience with the safety and efficacy of RR crops it has already successfully deregulated and have been planted in millions of acres for years. The Ninth Circuit affirmed the misplaced apprehension of the district court that there would be irreparable harm from deregulating GM plants and refused to think further than that.

Judge Smith of the Ninth Circuit, in his dissent, explains it well: "[I]nstead of giving deference to the agency's expertise, the majority gives deference to the district court, despite its wholesale rejection of the agency's proposal for an injunction and its failure to hold an evidentiary hearing." Pet.App.102a. In sum, the only entity with experience and historic factual knowledge of the issue was told to re-do its work—at much additional time and cost—to determine if RR alfalfa could be deregulated. The experience and knowledge of the United States government was thrown out and discounted without even an evidentiary hearing.

B. Certiorari Should Be Granted Because This Erroneous Presumption and Resulting Injunction Chills Scientific Advancement in an Industry That Needs More Technology, Not Less, and Causes Significant Unjustified Economic Losses.

The district court order, affirmed by the Ninth Circuit, enjoined *all* planting of RR alfalfa, for hay or seed, even in locations where there is no organic or conventional alfalfa for hundreds of miles. *See, e.g.*, Pet.App.221a. The effect of this injunction—in place since 2007—is a major step backwards in an industry which needs more technology, not less, to meet the challenges of feeding a world facing a booming population growth, a demand for bio-fuels, and the challenges brought by climate change. By clouding and confusing the regulatory pathway for the introduction of new biotech crops, innovation and increases in desperately needed agricultural productivity will be victims of pseudo-science rather than research and reason.

This is devastating to United States farmers, American consumers and the thousands who die each day from hunger and malnutrition. Norman E. Borlaug, *Farmers Can Feed the World* (visited November 21, 2009) <http://online.wsj.com/article/SB10001424052970203517304574304562754043656.html> (25,000 people die in the world per day from malnutrition). Indeed, in the United States and internationally, the call is for more GM crops not less. *See* New York Times, Opinion, May 24, 2004, *A Call for a Gene Revolution* (visited Nov. 22, 2009) <http://www.nytimes.com/2004/05/24/

opinion/24MON3.html?scp=1&sq=a%20Call%20for%20a%20gene%20revolution&st=cse>; *see also* Telegraph.co.uk, *GM Crops Must Be Grown in Britain, Royal Society Says* (visited Nov. 22, 2009) http://www.telegraph.co.uk/earth/earthnews/6387540/GM-crops-must-be-grown-in-Britain-Royal-Society-says.html ("The world needs genetically modified crops both to increase food yields and minimize the environmental impact of farming"). The United Kingdom's leading scientists have said British farmers must cultivate a new generation of genetically modified (GM) "supercrops" to prevent a global food crisis. *Id.*; *see also* Jonathan Rauch, "*Will Frankenfood Save the Planet?*," The Atlantic Monthly, October 2003, at 292 ("Over the next half century genetic engineering could feed humanity and save a raft of environmental ills—if only the environmentalists would let it").

Petitioner Monsanto submitted sample declarations from 17 farmers explaining the substantial losses they would suffer from a ban on RR alfalfa planting. Pet.App.267a-269a. An agricultural economist below estimates those losses at more than $200 million. Pet.App.267a-269a. PhytaGro believes this estimate of the adverse economic impact of the injunction is probably low—and for small companies like PhytaGro it can be devastating because the ban in the United States means that overseas alfalfa markets will not see GM alfalfa either, further limiting innovation. Counties like Argentina, for example, where as much as 4.5 million acres of alfalfa is grown,[22] have already adopted other

22. María A. Marino and Angel Berardo, *Alfalfa Forage Production under Different Phosphorus Supply Strategies* (visited Nov. 22, 2009) <http://www.ipni.net/ppiweb/bcrops.nsf/$webindex/6FA77B737A0682E7852570AE006C0056/$file/05-4p22.pdf>.

RR crops and yet will likely not see GM alfalfa until the United States ban is lifted. No doubt other major offshore alfalfa growing markets will also wait, causing problems with the world food supply and further economic losses to companies that seek to meet these needs.

The injunction has inflicted enormous injury to small companies like PhytaGro, as well as farmers who have made substantial investments in reliance on the government's regulatory approvals. *See also* Opening Brief of Federal Defendants-Appellants below at 41 ("RR alfalfa growers had made substantial investments in RR alfalfa by the time Geertson finally sought injunctive relief. . . .")

Monsanto is a major player in the development and marketing of GM crops in general, and the RR trait in particular. However, many other domestic and international companies have licensed and currently implement the Monsanto RR technology in their own germ plasm (seeds). Thus, the injunction—and its effective presumption of irreparable harm from the RR trait—has the affect of stalling the development and sale of similar products with all companies involved with GM alfalfa as well as the inevitable chilling effect on further GM development in the animal feed industry.

Indeed, the Ninth Circuit's decision has a chilling effect on all agricultural technology. The Ninth Circuit's decision makes broad injunctive relief essentially automatic whenever a district court finds a NEPA violation. The irreparable harm is deemed presumed and a full evidentiary hearing is deemed unnecessary.

Unjustified long-term nationwide injunctions against helpful GM agricultural products pose a significant threat to important government programs and will inflict enormous financial losses on private businesses and individuals that have reasonably relied on the government's regulatory approvals. *See* Federal Petition for Certiorari filed in *Amoco Prod. Co. v. Vill. of Gambell* (No. 85-1406), available at <http://www.usdoj.gov/osg/briefs/1985/sg850057.txt> (visited Nov. 22, 2009).

Within the next four decades, the world's famers will have to double production. Borlaug, *Farmers Feed the World*, *supra*. This increased need to grow food will occur on an ever-shrinking land base and in the face of environmental challenges caused by climate change. (Borlaug, *Farmers Feed the World*, *supra*, citing Oxfam study.) To accomplish this task of feeding so many, governments must support new science, such as genetically modified plants, and not block such necessary developments with political agendas. *Id.* The Ninth Circuit decision is dangerous precedent and should be reviewed so crucial agricultural science can develop and meet the challenge of feeding the world's hungry.

IV. CONCLUSION

Amicus curiae PhytaGro therefore strongly urges this Court to grant Petitioners' request for review. The petition for a writ of certiorari should be granted.

Respectfully submitted,

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AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
NOV 23 2009
OFFICE OF THE CLERK

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO CO., *et al.*,
Petitioners,

v.

GEERTSON SEED FARMS, *et al.*,
Respondents.

On Petition for a Writ of Certiorari To the United States Court of Appeals For the Ninth Circuit

AMICUS CURIAE BRIEF OF WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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Date: November 23, 2009

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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INTEREST OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this Court as well as other federal and state courts to urge them to abide by traditional restraints on the grant of injunctive relief, including refraining from granting an injunction unless the plaintiffs can demonstrate that it is necessary to prevent irreparable harm. *See, e.g., Winter v. Natural Resources Defense Counsel, Inc.*, 129 S. Ct. 365 (2008); *National Audubon Society v. Dep't of Navy*, 422 F.3d 174 (4th Cir. 2005).

The Court's decision in *Winter* strongly reaffirmed those traditional limitations on the courts' equitable powers. *Winter* made clear that the grant of jurisdiction to ensure compliance with a statute does not suggest that a federal court must grant any and all remedies designed to force compliance, and courts should not lightly assume that Congress – when adopting such statutes – intended to depart from established principles regarding equitable relief.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than the *amicus* and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for *amicus* provided counsel for Respondents with notice of intent to file. All parties have consented to this filing; letters of consent have been lodged with the Court.

WLF is concerned that the decision below, if allowed to stand, will effectively limit *Winter* to cases raising NEPA issues in a national security context.[2] It threatens to make nationwide injunctions virtually automatic in NEPA cases arising in all other contexts, despite the absence of any language in NEPA suggesting that Congress has directed federal courts to depart from traditional limitations on equitable relief whenever they find a NEPA violation. Although *Winter* arose in a national security context (the plaintiff sought to enjoin a program designed to detect the presence of enemy submarines), WLF does not believe that anything in the *Winter* decision suggests that the Court intended its interpretation of NEPA to apply only in that context. WLF believes that injunctive relief is particularly inappropriate when, as here, the trial court has not conducted an evidentiary hearing for the purpose of gathering evidence regarding the balance of harms.

STATEMENT OF THE CASE

WLF adopts and incorporates Petitioners' statement of the case.

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[2] NEPA (the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321 *et seq.*) requires preparation of an environmental impact statement (EIS) in connection with every "major federal action significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). The Ninth Circuit held that: (1) the Animal and Plant Health Inspection Service (APHIS) undertook such a "major federal action" when it granted a petition to afford Nonregulated Status to a variety of alfalfa known as Roundup Ready alfalfa (RRA); (2) APHIS violated NEPA by failing to prepare an EIS before granting the petition; and (3) the district court properly enjoined the planting of RRA until an EIS could be prepared. Pet. App. 1a-26a, 80a-103a.

REASONS FOR GRANTING THE PETITION

The Ninth Circuit has improperly conflated the role of federal courts in deciding the propriety of injunctive relief in environmental cases with the role of administrative agencies in evaluating the environmental impacts of their actions under federal law. Determining when injunctive remedies are appropriate in any case requires a judicial balancing of relative harms to the parties and the public interest. That determination must be made by a court on the basis of an evidentiary hearing. It cannot be deferred to a future administrative process undertaken by a government agency for entirely different statutory purposes.

This Court has consistently held, most recently in *Winter v. National Resources Defense Council, Inc.*, 129 S. Ct. 365 (2008), that lower courts must conduct their own equitable balancing of harm when granting injunctive relief. In this case, however, the Ninth Circuit approved a determination by the district court to avoid this requirement in light of its separate determination that an EIS must be prepared to satisfy the separate statutory requirements of NEPA. In doing so, the Ninth Circuit effectively adopted an exception to the judicial balancing requirement that has never before been recognized.

The purpose of an EIS is to provide a full and fair discussion of the significant environmental impacts of government action and to inform decision makers and the public of reasonable alternatives that address those impacts. In contrast, the judicial balancing of harm based on an evidentiary hearing protects "...the cardinal

principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings." *United States v. Microsoft Corp.*, 253 F.3d 34, 101 (D.C. Cir. 2001).

The need for an administrative agency to prepare an EIS under NEPA cannot relieve a court of its duty to conduct an evidentiary hearing as the basis of an equitable analysis of harm. The Ninth Circuit disregarded that important rule by approving the decision of the district court in this case.

I. THE NINTH CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH THIS COURT'S CONSISTENT APPROACH TOWARD THE APPLICATION OF INJUNCTIVE REMEDIES

In approving the decision of the district court in this case, the Ninth Circuit purported to apply the traditional four-factor test for the issuance of a permanent injunction, as required by *eBay v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). Pet. App. 10a. The Ninth Circuit recognized that this test requires a plaintiff to show "'(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of the hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'" Pet. App. 11a (citing *N. Cheyenne Tribe v. Norton*, 503 F.3d 836, 843 (9th Cir. 2007) (quoting *eBay*, 547 U.S. at 391)). The Ninth

Circuit also acknowledged that issuance of permanent injunctive relief "in the environmental context" requires a balancing of the harms identified in these four factors, citing *Forest Conservation Council v. U.S. Forest Serv.*, 66 F.3d 1489, 1496 (9th Cir. 1995); *Lands Council v. McNair*, 537 F.3d 981, 1005 (9th Cir. 2008) (en banc) ("Our law does not ... allow us to abandon a balance of harms analysis just because a potential environmental injury is at issue...."). *Id.*

While acknowledging the need to balance harms under the four-factor test as a general matter, the Ninth Circuit nevertheless declined to require it in this case. Instead, it choose to allow a broad permanent injunction against the future use of RRA until APHIS could prepare a full environmental impact report. Pet. App. 15a. In granting the injunction, the district court ignored expert evidence submitted by APHIS to show that a broad injunction was not necessary to address the harms for which the injunction was sought. *Id.* The Ninth Circuit nevertheless upheld the district court's decision, finding that the "district court did not abuse its discretion in choosing to reject APHIS's proposed mitigation measures in favor of a broader injunction to prevent more irreparable harm from occurring." Pet. App. 16a. In doing so, the Ninth Circuit effectively abdicated its responsibility for conducting the kind of judicial balancing of harms that this Court consistently has required as the basis for awarding injunctive relief. The Ninth Circuit's ruling flatly contradicts this Court's long-standing requirement that courts fully and independently assess the potential for harm when approving injunctive remedies in environmental cases. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311–12

(1982) (rejecting "'absolute statutory obligation'" to enjoin violations of environmental statutes) (citation omitted); *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542-45 (1987) (reversing Ninth Circuit presumption of irreparable harm in environmental cases).

This Court recently affirmed the requirement that courts conduct their own equitable balancing of harm when allowing injunctive relief with its decision last Term in *Winter v. National Resources Defense Council, Inc.*, 129 S. Ct. 365 (2008). In *Winter*, the Court rejected the view adopted by the district court and the Ninth Circuit that when a plaintiff demonstrates a strong likelihood of prevailing on the merits, a preliminary injunction may be entered based only on a "possibility" of irreparable harm. *Id.* at 375. Instead, the Court made clear that "[o]ur frequently reiterated standard" requires that plaintiffs seeking injunctive relief must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Id.* (citing *Los Angeles v. Lyons*, 461 U.S. 488, 502 (1974); *Granny Goose Foods, Inc. v. Teamsters*, 415 U.S. 423, 441 (1974); *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974)); *see also* 11A C. Wright, A. Miller, & M. Kane, *Federal Practice and Procedure* § 2948.1, p. 139 (2d ed. 1995) (applicant must demonstrate that in the absence of a preliminary injunction "the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered"); *id.* at 155 ("a preliminary injunction will not be issued simply to prevent the possibility of some remote future injury").

As in the present case, the lower courts in *Winter*

sustained the imposition of broad injunctive relief without considering whether lesser restrictions would be sufficient to protect against the harm the injunction was intended to address. At issue in *Winter* was the propriety of restrictions on the use by the U.S. Navy of active underwater sonar in certain naval training exercises. *Winter*, 129 S. Ct. at 370. Originally, a total of six such restrictions were imposed by the district court; however, by the time of the district court's final decision, the Navy was challenging only two of the original six restrictions. *Id.* at 373. The district court declined to reconsider the likelihood of irreparable harm in light of the four restrictions not challenged by the Navy. *Id.* at 374. Nevertheless, the Ninth Circuit affirmed the district court's conclusion that plaintiffs had established a "near certainty" of irreparable harm in the absence of broad injunctive relief. *Id.*

The Ninth Circuit's "presumption" that a broad injunctive remedy was necessary to prevent irreparable harm in the *Winter* case is analogous to its "presumption" in the present case that a broad injunction is necessary pending completion of an environmental impact analysis by APHIS of its approved use of RRA. In neither case is the application of the presumption consistent with this Court's required use of the four-factor equitable balancing test in determining when injunctive relief is appropriate in any case. Under the Ninth Circuit's decision, a court can avoid the necessary, though perhaps difficult, task in environmental cases of equitably balancing relative harm to the parties. The court can mandate broad injunctive relief with the hope that a government agency will perform the same task in preparing an EIS at some

indeterminate later date.

If allowed to stand, the Ninth Circuit's decision will undermine the fundamental framework established by the federal courts to determine whether and when the remedy of permanent injunctive relief should be available. This court should therefore grant review of the Ninth Circuit's decision consistent with its decision in *Winter* and the long line of cases that preceded it.

II. THE NINTH CIRCUIT'S DENIAL OF AN EVIDENTIARY HEARING WHEN AWARDING INJUNCTIVE RELIEF IN NEPA CASES WARRANTS THIS COURT'S REVIEW

Separate and apart from its failure to correctly apply the traditional test of balancing harm to determine when permanent injunctive remedies are appropriate, the Ninth Circuit also failed to allow the parties a sufficient opportunity to present evidence concerning whether such remedies were appropriate *at all* in this case.

Rather than basing its decision on an evidentiary hearing, which would allow it to assess the viability of witness opinions and resolve disputes between the parties' witnesses, the district court held that such a hearing "'would require this Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS.'" Pet. App. 17a. Citing *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 831 (9th Cir. 2002), the district court concluded that it "did not need to conduct an extensive inquiry, involving scientific

determinations, to determine what interim measures are necessary to protect the environment 'while the [government] conducts studies in order to make the very same scientific determinations.'" *Id.* On that basis, the district court determined that it need not conduct an evidentiary hearing before granting permanent injunctive relief, and the Ninth Circuit upheld the district court's determination. Pet. App. 20a.

The Ninth Circuit acknowledged that "generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed." Pet. App. 17a (citing *United States v. Microsoft*, 253 F.3d at 101–03; *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). "The fundamental requisite of due process of law is the opportunity to be heard." *Grannis v. Ordean*, 234 U.S. 385, 394 (1914). This basic notion of due process underpins the evidentiary hearing requirement. *SEC v. Smyth*, 420 F.3d 1225, 1232 (11th Cir. 2005). Yet the Ninth Circuit's decision would carve out a significant exception to this requirement in cases brought under NEPA.

A. Analysis of Environmental Impacts Under NEPA Cannot Substitute for an Evidentiary Hearing to Establish Grounds for Injunctive Relief

The Ninth Circuit upheld the district court's decision not to conduct an evidentiary hearing because it "would require [the court] to perform the same type of extensive inquiry into environmental effects that the

ordered EIS will require the government agency to perform." Pet. App. 18a. The district court concluded that it should not have to conduct an evidentiary hearing because the analysis involved complex technical issues more within the scope of the government's expertise.[3] This conclusion ignores the fundamental distinction between the government's obligation to comply with the administrative requirements of NEPA and the court's separate obligation to respect the parties' procedural due process rights in a judicial context – as the courts have elsewhere acknowledged, "[a] hearing on the merits . . . does not substitute for a relief-specific evidentiary hearing . . . ." *United States v. Microsoft*, 253 F.3d at 101.

The analysis of the lower courts on this point is wrong as a matter of law. "The purpose of an environmental impact statement [under NEPA] is to provide full and fair discussion of significant environmental impacts and to inform decision makers and the public of reasonable alternatives that would minimize adverse environmental impacts." *California ex rel. Lockyer v. U.S. Dept. of Agriculture*, 575 F.3d 999, 1012 (9th Cir. 2009). In contrast, an evidentiary hearing protects "the cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings." *United*

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[3] The district court's response to the parties' respective evidentiary submissions highlights the court's failure to conduct the necessary analysis and balancing of harms: "Essentially is [sic] the argument that I could be like a super environmental agency engaged in balancing all of these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And, number two, it isn't my job." Pet. App. 417a.

States v. Microsoft, 253 F.3d at 101. APHIS' execution of its duty to prepare an EIS did not and could not relieve the court of its duty to conduct an evidentiary hearing as the basis of an equitable analysis of harm. The court cannot escape its legal responsibility merely because an administrative agency may engage in a similar task.[4]

In order for the court to balance the harms, a court must assess not only the alleged harm to the environment, but also the harm to the parties in the action. *See Ocean Advocates v. U.S. Army Corps of Engineers*, 402 F.3d 846, 875 (9th Cir. 2005) (instructing the district court to conduct an evidentiary hearing to consider the effect a pier extension would have on the environment and the harms the proposed builder would suffer under an injunction). As this Court has recognized, "it is the duty of a court of equity granting injunctive relief to do so upon conditions that will protect all . . . whose interests the injunction may affect." *Inland Steel Co. v. United States*, 306 U.S. 153, 157 (1939); *Sharum v. Whitehead Coal Mining Co.*, 223 F. 282, 291 (8th Cir. 1915) ("There is no question about the right and duty of a court in issuing injunctions to take into consideration the comparative injury of the different parties to the suit.").

In the present case, the district court granted

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[4] But the district court in this case assumed as much: "So I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it, you know, all the measures and so forth. We allow the government in the first instance to do that." Pet. App. 417a.

injunctive relief based solely on its merits opinion that APHIS must prepare an EIS to evaluate the environmental impacts of it approving the use of RRA. That alone is not enough to meet the standards set by this Court.

B. There Is No Exception to the Requirement for an Evidentiary Hearing in NEPA Cases

It is well established that an evidentiary hearing is required before injunctive relief can be granted. *Charlton*, 841 F.2d at 989 ("Generally 'the entry of continuation of an injunction requires a hearing.'") (quoting *Professional Plan Examiners of New Jersey, Inc. v. Lefante*, 750 F.2d 282, 288 (3d Cir. 1984)); *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1311–12 (11th Cir. 1998) ("'Where the injunction turns on the resolution of bitterly disputed facts, ... an evidentiary hearing is normally required to decide credibility issues.'") (quoting *All Care Nursing Service v. Bethesda Memorial Hospital, Inc.*, 887 F.2d 1535, 1538 (11th Cir. 1989)); *Huntington v. Marsh*, 884 F.2d 648, 654 (2d Cir. 1989) (concluding the district court erred by failing to hold an evidentiary hearing prior to granting an injunction); *United States v. McGee*, 714 F.2d 607, 613 (6th Cir. 1983) ("Normally, an evidentiary hearing is required before an injunction may be granted."); *United States v. Production Plated Plastics, Inc.*, 762 F. Supp. 722, 728 (W.D. Mich. 1991) ("[A]n evidentiary hearing is normally required before injunctive relief may be granted.").

Courts have recognized only two narrow

exceptions to the general rule requiring an evidentiary hearing: (1) when there are no material facts in dispute, and (2) when an adverse party has waived its right to a hearing. *Charlton*, 841 F.2d at 989. Neither of these exceptions applies in the present case. *See* Pet. App. 21a (Smith, J. dissenting) (explaining that factual disputes exist and that petitioners did not waive their rights to a hearing). The fact that a government agency has been directed to conduct its own separate fact-finding process, pursuant to a separate statutory authority (in this case, NEPA) and subject to separate substantive and procedural requirements, provides no justification for any departure from the general rule.

The lower court's decision not to require an evidentiary hearing before granting a permanent injunction in this case reflects a failure to distinguish between the finding that the government had violated NEPA and the court's independent duty to make an evidentiary determination of irreparable harm. The Second Circuit addressed the same mistake in *Huntington v. Marsh*, 884 F.2d 648, 654 (2d Cir. 1989), where the district court also refused to hold an evidentiary hearing sought by the defendant to determine whether an injunction was appropriate. The Second Circuit noted that "the district court appears to have ruled that the establishment of a statutory violation, without more, warranted an injunction." *Id.* The Second Circuit made clear that the lower court had improperly failed to give necessary consideration "to the question of whether plaintiff had met its burden to establish some actual or threatened injury," an inquiry which should have occurred at an evidentiary hearing. *Id.* The Second Circuit's conclusion in the *Huntington*

case applies equally in NEPA cases, where statutory violations are procedural in nature. *See Winter*, 129 S. Ct. at 381 (2008) ("[T]he ultimate legal claim is that the Navy must prepare an EIS, not that it must cease sonar training.").

The Ninth Circuit should have reversed the district court in the absence of an evidentiary hearing on harm to the parties. It did not do so, and its error warrants review by this Court.

CONCLUSION

For these reasons, *amicus curiae* WLF urges the Court to grant the Petition for Writ of Certiorari in this action and reverse the judgment below.

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JOINT APPENDIX

Supreme Court, U.S.
FILED
MAR 1 - 2010
OFFICE OF THE CLERK

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
Petitioners,
v.
GEERTSON SEED FARMS, ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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ITEMS PREVIOUSLY REPRODUCED

In accordance with Supreme Court Rule 26.1, the following items have been omitted in printing this joint appendix because they appear on the following pages of the Appendix to Petition for Writ of Certiorari filed on Ocotber 22, 2009 by Petitioners in Case No. 09-475.

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RELEVANT DOCKET ENTRIES

U.S. Court of Appeals for the Ninth Circuit
Case No. 07-16458

Date Filed	#	Docket Text
08/16/2007	1	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N): n. setting schedule as follows: appellant's designation of RT is due 8/23/07; appellee's designation of RT is due 9/4/07,, ; appellant shall order transcript by 9/12/07; court reporter shall file transcript in DC by 10/15/07,, ; certificate of record shall be filed by 10/22/07 ; appellant's opening brief is due 11/29/07; appellees' brief is due 12/31/07,, ; appellants' reply brief is due 1/14/08; [07-16458] (GR)
08/16/2007	2	filed notice of representation of Holly J. Tate, Philip J. Perry, Janice M. Schneider, J. Thomas Carrato, Rachel Gold Lattimore and Stanley H. Abramson as counsel for apit [07-16458] (GR)
08/16/2007	3	Filed Holly J. Tate Civil Appeals Docketing Statement served on 8/10/07 (to CONFATT) [07-16458] [07-16458] (GR)
08/16/2007	4	Filed Appellants' joint motion to expedite appeal. [07-16458]

		served on 8/16/07 (to PROMO) (RT)
		* * *
08/23/2007	8	Filed order CONFATT (vs) This case is under consideration for incl in the mediation program. Within 14 days of this order, counsel for all parties intending to file br in this matter are requested to inform Roxanne G. Ashe, circuit mediator, in writing by fax of their clients' views on whether the case is appropriate for settlement discussions or mediation...The existing br sched remains in effect... [07-16458] (GR)
08/23/2007	11	Received Appellant Monsanto Company's notice of designation of reporter's transcript. (hearing dates: 6/30/06, 1/19/07, 3/5/07, 3/8/07, 4/27/07 & 6/22/07) (CASEFILE) [07-16458] (RT)
08/27/2007	9	Filed Appellee Center for Food Safety's opposition to appellants' joint motion to expedite appeal [4] served on 8/27/07 (to PROMO) [07-16458] (RT)
		* * *
08/30/2007	12	Filed Forage Genetics, Inc, et al's joint reply in support of motion to expedite appeal [4] in 07-16458 ;

		served on 8/30/07 (PROMO) [07-16458, 07-16492] (MF)
09/11/2007	13	Filed order (Deputy Clerk: lbs /PROMO) The crt sua sponte consolidates nos 07-16458 & 07-16492. Intv aplt Monsanto Com's opposed mtn for expedition is DENIED. The brfg schedule established on 8/22/07 in 07-16492 shall govern these consolidated appeals. [07-16458, 07-16492] (MF)
09/19/2007	16	Filed Appellants' motion to reconsider order of the Court of 9/11/07; served on 9/19/07 (to PROMO) [6297850] [07-16458, 07-16492] (RT)
09/20/2007	15	Filed order CONFATT (RGA) The court has determined that these appeals will not be selected for inclusion in the Mediation Program. [07-16458, 07-16492] (RT)
09/28/2007	17	Filed Appellees' Geerton Seed Farms, et al.'s, opposition to appellant's motion to reconsider order of the Court; served on 9/28/07 (to PROMO) [07-16458, 07-16492] (RT)
10/03/2007	18	Filed Appellants' reply in support of their motion to reconsider order of the Court [16] served on 10/3/07 (to PROMO) [07-16458, 07-16492] (RT)

10/15/2007	22	Filed order (Appellate Commissioner) Intervenor Appellant Monsanto Company's opposed motion for reconsideration is granted in part and denied in part. The briefing schedule established on August 22, 2007 in no. 07-16492 remains in effect. The Clerk shall calendar these consolidated appeals as soon as possible after briefing is complete. (PROMO) [07-16458, 07-16492] (RT)
10/23/2007	24	Filed Trask Family Seeds motion to consolidate cases [07-16725, 07-16458, 07-16492] served on 10/23/07 [6327086] PROMO (GR)
10/29/2007	25	Filed intevenor appellants' Forage Genetics, et al.'s partial opposition to motion to consolidate cases [24] served on 10/29/07 (to PROMO) [07-16458, 07-16492, 07-16725] (RT)
10/31/2007	26	Filed Appellees Geerton Seed Farms, et al.'s, reply ins support of motion to connsolidate cases [24] served on 10/31/07 (to PROMO) [07-16458, 07-16492, 07-16725] (RT)
11/02/2007	27	Filed (federal) Appellants Mike Johanns, et al.'s, response to appellee's motion to consolidate cases [24]; served on 11/1/07 (to PROMO) [07-16458, 07-16492, 07-

		16725] (RT)
11/08/2007	28	Filed Appellee reply to aplt's response to appellee's motion to consolidate cases ;served on 11/8/07 (PROMO) [07-16725, 07-16458, 07-16492] (SW)
11/15/2007	30	Filed order (Deputy Clerk: lbs) Plaintiffs' partially opposed mtn to consolidate 07-16725 with nos. 07-16458 and 07-16492 is granted. The briefing schedule established on 9/26/07 in no. 07-16725 shall govern these consolidated appeals. [07-16458, 07-16492, 07-16725] (KKW)
01/07/2008	32	Filed original and 15 copies def/intervenor/aplts opening brief (Informal: no) 59 pages (aplts filed joint excerpts) ; served on 1/4/08 [07-16458, 07-16492, 07-16725] (CW)
01/08/2008	31	Filed original and 15 copies federal aplts Mike Johanns, Ron Dehaven, Steve Johnson in 07-16725 opening brief (Informal: no) 47 pages and five excerpts of record in 4 vols; served on 1/4/08 [07-16458, 07-16492, 07-16725] (CW)
01/11/2008	33	Filed original and 15 copies American Farm Bureau Federation's amicus curiae brief (brief states all parties consent to its filing) of 14 pages in support of

		appellants; served on 1/10/08 [07-16458, 07-16492, 07-16725] (RT)
		* * *
01/24/2008	37	Filed notice of joint brief by all Appellees, Circuit Rule 28-4. Briefing schedule is now as follows: aplee's brief due 2/25/08 for all Appellees and Five additional pages are authorized for aplee(s) only. (CASEFILE) [07-16458, 07-16492, 07-16725] (RT)
		* * *
02/25/2008	38	Filed original and 15 copies appellees Geerton Seed Farms, et al., 69 pages joint answering brief, 1 vol. of Supp EOR; served on 2/25/08 [07-16458, 07-16492, 07-16725] (RT)
		* * *
03/06/2008	44	Received original and 15 copies of Amicus Curiae Arkansas Rice Growers Association's brief in 16 pages. Deficiency: Motion pending e. Served on. 03/03/2008 Notified counsel. [07-16725, 07-16458, 07-16492] (GN)
03/06/2008	56	Amicus briefs from Arkansas Rice Growers Assn. sent to Panel on 5/29/08. [07-16725, 07-16458, 07-16492] (GN)

* * *

03/21/2008	51	Filed original and 15 copies of Appellants Ron Dehaven, Mike Johanns and Steve Johnson in 07-16725 (Informal: No) reply brief of 28 pages.. Served on. [07-16458, 07-16725, 07-16492] (FT)

* * *

03/27/2008	49	Filed Intervenor-Appellant's Forage Genetics, Inc,John Grover in 07-16458, Daniel Mederos supplemental excerpts of record on appeal in 1 volumes. [07-16458, 07-16725, 07-16492] (FT)
03/27/2008	50	Filed original and 15 copies of Appellants Forage Genetics, Inc. and John Grover, Daniel Mederos, Mark Watte (Informal: No) reply brief of 31 pages.. Served on 03/20/2008. [07-16458, 07-16725, 07-16492] (FT)

* * *

05/02/2008	55	FILED (ORIGINAL) CERTIFIED RECORD ON APPEAL.. 1 clks vol and 1 expando folder dkt #s 137,183,204,239,256 (KM)

* * *

06/03/2008	58	UPDATED CASE CALENDARED: 06/10/2008 9:00 AM San Francisco, CA

		Courtroom 1 (AW)
06/10/2008	59	ARGUED AND SUBMITTED TO MARY M. SCHROEDER, N. RANDY SMITH and VALERIE BAKER FAIRBANK. [07-16458, 07-16725, 07-16492] (GB)
07/09/2008	60	Filed Monsanto Company's additional citations. Served on 07/08/2008. (fedex to panel) [07-16458, 07-16725, 07-16492] (EL)
07/18/2008	61	Filed Appellees' additional citations. Served on 07/17/2008. (faxed to panel) [07-16458, 07-16725, 07-16492] (RL)
09/02/2008	62	FILED OPINION (MARY M. SCHROEDER, N. RANDY SMITH and VALERIE BAKER FAIRBANK) AFFIRMED. FILED AND ENTERED JUDGMENT. [07-16458, 07-16725, 07-16492] (RP)
10/17/2008	63	Filed (ECF) Appellant Monsanto Company in 07-16458 petition for panel rehearing and petition for rehearing en banc (from 09/02/2008 opinion). Date of service: 10/17/2008. [6677750] [07-16458, 07-16725, 07-16492] (MM)
		* * *
10/31/2008	66	Filed order (MARY M. SCHROEDER, N. RANDY SMITH and VALERIE BAKER FAIRBANK) Within 21 days

		from the date of this order, plaintiffs-appellees are directed to file a response to the petition for panel rehearing and suggestion for rehearing en banc filed by intervenor-appellants Monsanto Company, Forage Genetics International, LLC, John Grover, Daniel Mederos, and Mark Watte on October 17, 2008. An original and 50 copies of the responses shall be filed with the Clerk of Court, and shall not exceed 15 pages. [07-16458, 07-16725, 07-16492] (WL)
11/19/2008	67	Filed (ECF) Appellant Monsanto Company citation of supplemental authorities. Date of service: 11/19/2008. [6711972] (MM)
11/21/2008	68	Filed (ECF) Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute, Dakota Resource Council, Geertson Seed Farms, National Family Farm Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16458, 07-16492, - Geertson Farms Inc. and Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute, Dakota Resource Council, Geertson Seed Farms, National Family Farm

		Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16725 response to Order , Order to set response by any party to anything, Combo PFR Panel and En Banc (ECF Filing) , for panel and en banc rehearing (panel, all active judges, any interested senior judges). Date of service: 11/21/2008. [6716008]. [07-16458, 07-16725, 07-16492] (GAK)
11/25/2008	69	Filed (ECF) - Geertson Farms Inc. and Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute, Dakota Resource Council, Geertson Seed Farms, National Family Farm Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16725, Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute, Dakota Resource Council, Geertson Seed Farms, National Family Farm Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16458, 07-16492 citation of supplemental authorities. Date of service:

		11/25/2008. [6719373] [07-16725, 07-16458, 07-16492] (GAK)
04/03/2009	70	Filed (ECF) - Monsanto Company in 07-16725, Appellant Monsanto Company in 07-16458, 07-16492 citation of supplemental authorities. Date of service: 04/03/2009. [6870770] [07-16725, 07-16458, 07-16492] (MM)
04/09/2009	71	Filed (ECF) Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute, Dakota Resource Council, Geertson Seed Farms, National Family Farm Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16458 citation of supplemental authorities. Date of service: 04/09/2009. [6877051] [07-16458, 07-16725] (GAK)
06/24/2009	72	Filed order and amended opinion (MARY M. SCHROEDER, N. RANDY SMITH and VALERIE BAKER FAIRBANK). The opinion and dissent filed September 2, 2008, and appearing at 541 F.3d 938 (9th Cir. 2008), are hereby amended. The amended opinion and dissent are filed concurrently with this Order. With these amendments, Judges Schroeder and Fairbank

		have voted to deny the petition for panel rehearing and recommend denial of the petition for rehearing en banc. Judge N.R. Smith votes to grant the petition for panel rehearing and rehearing en banc. The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35. The petition for panel rehearing and rehearing en banc is DENIED. No further petitions for rehearing will be accepted. [6966794] [07-16458, 07-16725, 07-16492] (RP)
07/07/2009	73	MANDATE ISSUED.(MMS, NRS and VBF) [6983128] [07-16458, 07-16725, 07-16492] (TB)
09/14/2009	74	Received letter from the Supreme Court dated 09/11/2009 re: the motion for an extension of time to file a petition for writ of certiorari is granted to 10/22/09. [7062912] [07-16725, 07-16458, 07-16492] (LC)
10/27/2009	75	Received notice from the Supreme Court: petition for certiorari filed on 10/23/2009. Supreme Court Number 09-475. [7109723] [07-16458, 07-16725, 07-16492] (TB)

01/25/2010	76	Received letter from the Supreme Court dated 01/15/2010. The petition for writ of certiorari is granted. The brief of petitioners is to be filed on or before Thursday, February 25, 2010. The brief of respondents is to be filed on or before Thursday, March 25, 2010. [7208856] [07-16458, 07-16725, 07-16492] (TB)

U.S. Court of Appeals for the Ninth Circuit
Case No. 07-16492

Date Filed	#	Docket Text
08/22/2007	1	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N): n. setting schedule as follows: appellant's designation of RT is due 8/27/07,, ; appellee's designation of RT is due 9/5/07,, ; appellant shall order transcript by 9/17/07,, ; court reporter shall file transcript in DC by 10/16/07; certificate of record shall be filed by 10/23/07 ; appellant's opening brief is due 12/3/07,, ; appellees' brief is due 1/2/08,, ; appellants' reply brief is due 1/15/08,, ; [07-16492] (GR)
08/22/2007	3	filed notice of representation of Martha C. Luemers and B. Andrew Brown as counsel for aplts [07-16492] (GR)
08/22/2007	4	Filed Martha C. Luemers in 07-16492 Civil Appeals Docketing Statement served on 8/16/07 (to CONFATT) [07-16492] [07-16492] (GR)

* * *

U.S. Court of Appeals for the Ninth Circuit
Case No. 07-16725

Date Filed	#	Docket Text
09/26/2007	1	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N): Y. setting schedule as follows: CADS is due 10/3/07,, ; appellant's designation of RT is due 9/28/07,, ; appellee's designation of RT is due 10/9/07,, ; appellant shall order transcript by 10/18/07,, ; court reporter shall file transcript in DC by 11/19/07,, ; certificate of record be filed by 11/26/07 ; appellant's opening brief is due 1/4/08,, ; appellees' brief is due 2/4/08,, ; appellants' reply brief is due 2/19/08,, ; [07-16725] (GV)
10/23/2007	2	Filed Trask Family Seeds motion to consolidate cases [07-16725, 07-16458, 07-16492] served on 10/23/07 [6327086] PROMO (GR)
10/26/2007	3	Filed Civil Appeals Docketing Statement served on 10/23/07 (to CONFATT) [07-16725] [07-16725] (GR)
		* * *
04/09/2009	52	Filed (ECF) Appellees Beyond Pesticides, Center for Food Safety, Cornucopia Institute,

Dakota Resource Council, Geertson Seed Farms, National Family Farm Coalition, Sierra Club, Trask Family Seeds and Western Organization of Resource Councils in 07-16458 citation of supplemental authorities. Date of service: 04/09/2009. [6877051] [07-16458, 07-16725] (GAK)

* * *

RELEVANT DOCKET ENTRIES

U.S. District Court for the Northern District of California
Case No. 3:06-cv-01075-CRB

Date Filed	#	Docket Text
02/16/2006	1	COMPLAINT against all defendants (Filing fee $ 250, receipt number 3381804.) SUMMONS ISSUED. Filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Geertson Farms Inc., Trask Family Seeds, Center for Food Safety. (mcl, COURT STAFF) (Filed on 2/16/2006) Additional attachment(s) added on 2/24/2006 (mcl, COURT STAFF). (Entered: 02/16/2006)
		* * *
04/05/2006	10	AMENDED COMPLAINT - *FIRST* against all defendants. Filed byGeertson Seed Farms, Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Center for Food Safety. (Rostov,

		William) (Filed on 4/5/2006) (Entered: 04/05/2006)
		* * *
04/24/2006	12	ANSWER to Amended Complaint byMike Johanns, Ron Dehaven. (Floom, Kristen) (Filed on 4/24/2006) (Entered: 04/24/2006)
		* * *
04/24/2006	13	MOTION to Dismiss *Plaintiffs' Fourth Claim for Relief* filed by Steve Johnson. Motion Hearing set for 6/30/2006 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order)(Floom, Kristen) (Filed on 4/24/2006) (Entered: 04/24/2006)
06/09/2006	19	JOINT CASE MANAGEMENT STATEMENT *and Proposed Order* filed by Mike Johanns, Ron Dehaven, Steve Johnson. (Floom, Kristen) (Filed on 6/9/2006) (Entered: 06/09/2006)
06/09/2006	20	Memorandum in Opposition *to Defendant EPA's Motion to Dismiss Plaintiffs' Fourth Claim For Relief* filed byBeyond Pesticides, Sierra Club, Center for Food Safety. (Attachments: # 1 Proposed Order Denying Motion to Dismiss)(Rostov,

		William) (Filed on 6/9/2006) (Entered: 06/09/2006)
		* * *
06/16/2006	21	Minute Entry: Initial Case Management Conference held on 6/16/2006 before Charles R. Breyer (Date Filed: 6/16/2006), CASE REFERRED to Magistrate Judge Elizabeth D. Laporte for Settlement Conference. Status Conference set for 9/8/2006 08:30 AM in Courtroom 8, 19th Floor, San Francisco. (Court Reporter - Not Reported.) (be, COURT STAFF) (Date Filed: 6/16/2006) (Entered: 06/16/2006)
06/16/2006	22	Reply to Opposition re 13 MOTION to Dismiss *Plaintiffs' Fourth Claim for Relief* filed bySteve Johnson. (Floom, Kristen) (Filed on 6/16/2006) (Entered: 06/16/2006)
		* * *
06/30/2006	26	Minute Entry: Motion Hearing held on 6/30/2006 before Charles R. Breyer (Date Filed: 6/30/2006) re 13 MOTION to Dismiss *Plaintiffs' Fourth Claim for Relief* filed by Steve Johnson,. (Court Reporter Kathy Wyatt.) (be, COURT STAFF) (Date

		Filed: 6/30/2006) (Entered: 06/30/2006)
07/26/2006	27	ORDER by Judge Charles R. Breyer granting 13 Motion to Dismiss (crblc2, COURT STAFF) (Filed on 7/26/2006) (Entered: 07/26/2006)
		* * *
09/01/2006	31	Minute Entry: Settlement Conference held with Magistrate Judge Laporte on 8/31/2006. Case did not settle. (lmh, COURT STAFF) (Date Filed: 9/1/2006) (Entered: 09/01/2006)
		* * *
09/11/2006	34	SECOND JOINT CASE MANAGEMENT STATEMENT filed by Mike Johanns, Ron Dehaven. (Attachments: # 1 Proposed Order # 2 Proposed Order)(Floom, Kristen) (Filed on 9/11/2006) Modified on 9/14/2006 (mcl, COURT STAFF). (Entered: 09/11/2006)
		* * *
09/22/2006	36	Minute Entry: Status Conference (Date Filed: 9/22/2006), Set Deadlines/Hearing as to (Date Filed: 9/22/2006). Responses due by 11/17/2006. Replies due by 12/15/2006. Motion Hearing set

		for 1/19/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Court Reporter - Not Reported.) (be, COURT STAFF) (Date Filed: 9/22/2006) (Entered: 09/22/2006)
		* * *
09/29/2006	38	NOTICE by Mike Johanns, Ron Dehaven of *Manual Filing of Administrative Record* (Attachments: # 1 Certificate of Service# 2 Index)(Floom, Kristen) (Filed on 9/29/2006) (Entered: 09/29/2006)
		* * *
10/20/2006	41	MOTION for Summary Judgment *and Memorandum of Points and Authorities* filed by Mike Johanns, Ron Dehaven. Motion Hearing set for 1/19/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order)(Floom, Kristen) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	42	MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra

		Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. Motion Hearing set for 1/19/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	43	Declaration of Kermit Carter in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	44	Declaration of Caroline Cox in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra

		Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	45	Declaration of Kathy Cox in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	46	Declaration of Carolyn Hinshaw in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family

		Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	47	Declaration of Dean Hulse in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	48	Declaration of Andrew Kimbrell in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related

		document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	49	Declaration of George A.("Tony") Loftin in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	50	Declaration of Paula Lomazzi in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006)

		(Entered: 10/20/2006)
10/20/2006	51	Declaration of Lee McSherry in Support of 43 Declaration in Support, filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 43) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	52	Declaration of Debra Moon in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	53	Declaration of Jim Munsch in Support of 42 MOTION for Summary Judgment

		Memorandum of Points and Authorities in Support Thereof filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	54	Declaration of Beth Pardieck in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	55	Declaration of Blaine Shmaltz in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof*

		filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	56	Declaration of Terry Shistar in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	57	Declaration of Patrick Trask in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota

		Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	58	Declaration of Robert Roy van de Hoek in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	59	Declaration of Lillian L. Wolfenbarger in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra

		Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	60	Declaration of Neil Carman in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	61	Declaration of Charles M. Benbrook in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of

		Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	62	Declaration of Phillip Geertson in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C)(Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	63	Declaration of William B. Rostov in Support of 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra

		Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C# 4 Exhibit D# 5 Exhibit E# 6 Exhibit F# 7 Exhibit G# 8 Exhibit H# 9 Exhibit H Tab 1# 10 Exhibit H Tab 2# 11 Exhibit H Tab 3)(Related document(s) 42) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	64	EXHIBITS re 63 Declaration in Support,, *Exhibit H Tab 4* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit H Tab 5# 2 Exhibit H Tab 6# 3 Exhibit H Tab 7# 4 Exhibit H Tab 8# 5 Exhibit H Tab 9# 6 Exhibit H Tab 10# 7 Exhibit H Tab 11# 8 Exhibit H Tab 12)(Related document(s) 63) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	65	EXHIBITS re 63 Declaration in Support,, *Exhibit H Tab 13* filed byBeyond Pesticides, Cornucopia

		Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit H Tab 14# 2 Exhibit Tab 15# 3 Exhibit H Tab 16# 4 Exhibit H Tab 17# 5 Exhibit Tab 18# 6 Exhibit Tab 19# 7 Exhibit H Tab 20# 8 Exhibit H Tab 21)(Related document(s) 63) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	66	EXHIBITS re 63 Declaration in Support,, *Exhibit H Tab 22* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit H Tab 23# 2 Exhibit H Tab 24# 3 Exhibit H Tab 25# 4 Exhibit H Tab 26# 5 Exhibit H Tab 27# 6 Exhibit H Tab 28# 7 Exhibit H Tab 29# 8 Exhibit H Tab 30)(Related document(s) 63) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	67	EXHIBITS re 63 Declaration in

		Support,, *Exhibit H Tab 31* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit H Tab 32# 2 Exhibit H Tab 33# 3 Exhibit H Tab 34# 4 Exhibit H Tab 35# 5 Exhibit H Tab 36# 6 Exhibit H Tab 37# 7 Exhibit H Tab 38# 8 Exhibit H Tab 39)(Related document(s) 63) (Rostov, William) (Filed on 10/20/2006) (Entered: 10/20/2006)
10/20/2006	68	EXHIBITS re 63 Declaration in Support,, *Exhibit H Tab 40* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit H Tab 41# 2 Exhibit H Tab 42# 3 Exhibit Tab 43# 4 Exhibit H Tab 44# 5 Exhibit H Tab 45# 6 Exhibit H Tab 46# 7 Exhibit H Tab 47# 8 Exhibit H Tab 48)(Related document(s) 63) (Rostov, William) (Filed on

		10/20/2006) (Entered: 10/20/2006)
10/26/2006	69	Proposed Order re 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 10/26/2006) (Entered: 10/26/2006)
		* * *
11/17/2006	73	Memorandum in Opposition re 41 MOTION for Summary Judgment and Memorandum of Points and Authorities filed byMike Johanns, Ron Dehaven, Steve Johnson. (Williams, Robert) (Filed on 11/17/2006) (Entered: 11/17/2006)
11/17/2006	74	Memorandum in Opposition re 41 MOTION for Summary Judgment *and Memorandum of Points and Authorities* filed byBeyond Pesticides, Cornucopia Institute, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for

		Food Safety. (Attachments: # 1 Proposed Order)(Rostov, William) (Filed on 11/17/2006) (Entered: 11/17/2006)
11/17/2006	75	Declaration of Joseph Mendelson III in Support of 74 Memorandum in Opposition, filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit B Tab 1# 4 Exhibit B Tab 2# 5 Exhibit B Tab 3# 6 Exhibit B Tab 4# 7 Exhibit B Tab 5# 8 Exhibit B Tab 6)(Related document(s) 74) (Rostov, William) (Filed on 11/17/2006) (Entered: 11/17/2006)
11/17/2006	76	EXHIBITS re 75 Declaration in Support,, *Exhibit B Tab 7* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit B Tab 8# 2 Exhibit B Tab

		9# 3 Exhibit B Tab 10# 4 Exhibit B Tab 11# 5 Exhibit B Tab 12# 6 Exhibit B Tab 13# 7 Exhibit Tab 14# 8 Exhibit Tab 15# 9 Exhibit B Tab 16# 10 Exhibit B Tab 17# 11 Exhibit B Tab 18# 12 Exhibit B Tab 19)(Related document(s) 75) (Rostov, William) (Filed on 11/17/2006) (Entered: 11/17/2006)
		* * *
12/15/2006	79	Reply to Opposition *to Defendants' Motion for Summary Judgment* filed byMike Johanns, Ron Dehaven, Steve Johnson. (Williams, Robert) (Filed on 12/15/2006) (Entered: 12/15/2006)
12/15/2006	80	Reply to Opposition *To Plaintiffs's Motion for Summary Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 12/15/2006) (Entered: 12/15/2006)
01/19/2007	81	Minute Entry: Motion Hearing held on 1/19/2007 before Charles R. Breyer (Date Filed: 1/19/2007) re 42 MOTION for Summary

		Judgment *Memorandum of Points and Authorities in Support Thereof* filed by Sierra Club,, Trask Family Seeds,, Center for Food Safety,, Beyond Pesticides,, Cornucopia Institute,, Dakota Resource Council,, National Family Farm Coalition,, Western Organization of Resource Councils,, Geertson Seed Farms,, 41 MOTION for Summary Judgment *and Memorandum of Points and Authorities* filed by Mike Johanns,, Ron Dehaven,. Motion Hearing set for 1/19/2007 02:00 PM in Courtroom 8, 19th Floor, San Francisco. (Court Reporter Kathy Powell.) (be, COURT STAFF) (Date Filed: 1/19/2007) (Entered: 01/19/2007)
01/19/2007	82	Minute Entry: Motion Hearing held on 1/19/2007 P.M.before Charles R. Breyer (Date Filed: 1/19/2007) re 42 MOTION for Summary Judgment *Memorandum of Points and Authorities in Support Thereof* filed by Sierra Club,, Trask Family Seeds,, Center for Food Safety,, Beyond Pesticides,, Cornucopia Institute,, Dakota Resource Council,, National Family Farm Coalition.,, Western

		Organization of Resource Councils,, Geertson Seed Farms,, 41 MOTION for Summary Judgment *and Memorandum of Points and Authorities* filed by Mike Johanns,, Ron Dehaven,. (Court Reporter Kathy Powell.) (be, COURT STAFF) (Date Filed: 1/19/2007) (Entered: 01/23/2007)
02/13/2007	83	ORDER by Judge Charles R. Breyer denying 41 Motion for Summary Judgment in part and dismissing without prejudice in part, granting 42 Motion for Summary Judgment in part and dismissing without prejudice in part. (crblc1, COURT STAFF) (Filed on 2/13/2007) (Entered: 02/13/2007)
		* * *
03/02/2007	86	MOTION to Intervene filed by Monsanto Company. Motion Hearing set for 4/6/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Exhibit 1: Tate Declaration# 2 Exhibit 2: Meyer Declaration# 3 Exhibit 3: McCaslin Declaration# 4 Exhibit 4: Tlucek Declaration# 5 Exhibit 5: Christiansen Declaration# 6 Exhibit 6: Freese Declaration# 7 Exhibit 7: Pierson

		Declaration# 8 Exhibit 8: Sharp Declaration# 9 Exhibit 9: Rogan Declaration# 10 Exhibit 10: Text of Proposed Order)(Tate, Holly) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	87	*(Proposed)* ANSWER to Amended Complaint byMonsanto Company. (Tate, Holly) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	88	MOTION to Intervene filed by Forage Genetics, Inc.. Motion Hearing set for 4/6/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Exhibit # 2 Exhibit Decl McCaslin Exh A# 3 Exhibit Decl McCaslin Exh B# 4 Exhibit Decl McCaslin Exh C# 5 Exhibit Decl McCaslin Exh D# 6 Exhibit Decl McCaslin Exh E# 7 Exhibit Decl McCaslin Exh F# 8 Exhibit Decl McCaslin Exh G# 9 Exhibit Decl McCaslin Exh H# 10 Exhibit Exh 2 Decl Lowry# 11 Exhibit Exh 3 Decl Kays# 12 Exhibit Exh 4 Certificate of Parties# 13 Exhibit Exh 5 Answer to Complaint# 14 Exhibit Exh 6 Atty Attestation# 15 Proposed Order)(Kays, David) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	89	Declaration of Neil Hoffman filed byMike Johanns. (O'Connor,

		Charles) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	90	Defendants' Motion to Approve Aphis' Proposed Judgment by Mike Johanns. (O'Connor, Charles) (Filed on 3/2/2007) Modified on 3/6/2007 (mcl, COURT STAFF). (Entered: 03/02/2007)
03/02/2007	91	Proposed Order *Judgment in a Civil Case* by Mike Johanns. (O'Connor, Charles) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	92	MOTION to Intervene filed by John Grover, Mederos Mederos, Mark Watte. Motion Hearing set for 4/6/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Exhibit Decl of Grover# 2 Exhibit Decl of Mederos# 3 Exhibit Decl of Watte# 4 Exhibit Decl Tiegs# 5 Exhibit Decl of Phillips# 6 Exhibit Decl of Waters# 7 Exhibit Decl of Kays# 8 Exhibit Certificate of Grover No Interests# 9 Exhibit Certificate of Mederos No Interests# 10 Exhibit Certificate of Watte of Interests# 11 Exhibit Answer to Complaint# 12 Exhibit Atty Signature Attestation# 13 Proposed Order Proposed Order)(Kays, David) (Filed on

		3/2/2007) (Entered: 03/02/2007)
03/02/2007	93	MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. Motion Hearing set for 4/6/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order Granting Plaintiffs' Motion for Final Relief, Permanent Injunction and Entry of Judgment# 2 Plaintiffs' Proposed Judgment)(Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	94	Declaration of Phillip Geertson in Support of 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety.

		(Attachments: # 1 Exhibit A)(Related document(s) 93) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	95	Declaration of William B. Rostov in Support of 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 93) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	96	Declaration of Blaine Shmaltz in Support of 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 93) (Rostov, William) (Filed on 3/2/2007)

		(Entered: 03/02/2007)
03/02/2007	97	Declaration of Marc Asumendi in Support of 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 93) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	98	Declaration of Vince Holtz in Support of 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 93) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)
03/02/2007	99	Declaration of Maury Johnson in Support of 93 MOTION for Permanent Injunction , *Final*

Relief and Entry of Judgment filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 93) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)

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03/02/2007	101	Declaration of William B. Rostov in Support of 100 MOTION to Shorten Time *For Plaintiffs' Motion for Final Relief, Permanent Injunction and Entry of Final Judgment and Defendant's Motion for Entry of Final Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 100) (Rostov, William) (Filed on 3/2/2007) (Entered: 03/02/2007)

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03/05/2007	108	ORDER re: hearing. Signed by Judge Charles R. Breyer on 3/5/2007. (crblc1, COURT STAFF) (Filed on 3/5/2007) (Entered: 03/05/2007)
03/05/2007	109	Minute Entry: Further Case Management Conference held on 3/5/2007 before Charles R. Breyer (Date Filed: 3/5/2007), Set Deadlines/Hearing as to 88 MOTION to Intervene, 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment*, 92 MOTION to Intervene, 86 MOTION to Intervene: (Date Filed: 3/5/2007). Motions Hearing set for 3/8/2007 10:30 AM. (Court Reporter James Yeomans.) (be, COURT STAFF) (Date Filed: 3/5/2007) (Entered: 03/06/2007)

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03/06/2007	115	MOTION for Entry of Judgment under Rule 54(b) filed by Mike Johanns. (O'Connor, Charles) (Filed on 3/6/2007) (Entered: 03/06/2007)
03/07/2007	116	Memorandum in Opposition re 100 MOTION to Shorten Time For *Plaintiffs' Motion for Final Relief, Permanent Injunction and Entry of Final Judgment and Defendant's Motion for*

		Entry of Final Judgment, 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment , and Defendants' Motion to Approve Proposed Judgment* filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Exhibit 1: Second Declaration of Mark H. McCaslin# 2 Exhibit 2: Proposed Order)(Tate, Holly) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	117	OBJECTIONS to re 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment (Objections to Plaintiffs' Declarations)* by Monsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Tate, Holly) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	118	Memorandum in Opposition *Defendants' Opposition to Plaintiffs' Motion for Final Relief, Permanent Injunction, and Entry of Judgment* filed byMike Johanns. (O'Connor, Charles) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	119	Memorandum in Opposition *to Defendants' Motion to Approve APHIS' Proposed Judgment* filed

		byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order)(Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	120	Proposed Order *Judgment in A Civil Case* by Mike Johanns. (O'Connor, Charles) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	121	DECLARATION of Brent Evans *in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	122	DECLARATION of Chep Gauntt *in Support of Plaintiffs' Opposition to Defendants' Motion*

		to Approve APHIS' Proposed Judgment filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Rostov, William) (Filed on 3/7/2007) Additional attachment(s) added on 3/27/2007 (mcl, COURT STAFF). (Entered: 03/07/2007)
03/07/2007	123	DECLARATION of Naonori Oishi *in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	124	DECLARATION of William Freese *in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed*

		Judgment filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit B# 2 Exhibit C# 3 Exhibit D# 4 Exhibit E# 5 Exhibit F)(Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	125	DECLARATION of Glenn Page *in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	126	Memorandum in Opposition to *Motions to Intervene* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm

		Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order Denying Motion to Intervene of Forage Genetics, Inc.# 2 Proposed Order Denying Monsanto Grover et al. Motion to Intervene# 3 Proposed Order Denying Monsanto Motion to Intervene)(Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	127	Exhibits re*Second Declaration of Neil Hoffman* filed byMike Johanns. (Attachments: # 1 UC Davis Publication# 2 Crop Science Vol 45# 3 Alfalfa Gene Flow# 4 Population Ecology Vol 28# 5 Summary of 2000 Exp)(O'Connor, Charles) (Filed on 3/7/2007) Modified on 3/12/2007 (mcl, COURT STAFF). (Entered: 03/07/2007)
03/07/2007	128	Declaration of Neil Hoffman *Second Declaration of Neil Hoffman* filed byMike Johanns. (O'Connor, Charles) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	129	Declaration of Chep Gauntt *[errata]in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed*

		Judgment filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 122) (Rostov, William) (Filed on 3/7/2007) Modified on 3/12/2007 (mcl, COURT STAFF). (Entered: 03/07/2007)
03/07/2007	130	DECLARATION of Naonori Oishi *[errata]in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/07/2007	131	EXHIBITS re 122 Declaration in Opposition, *[errata-2]in Support of Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* filed

		byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 122) (Rostov, William) (Filed on 3/7/2007) (Entered: 03/07/2007)
03/08/2007	132	Minute Entry: Motion Hearing held on 3/8/2007 before Charles R. Breyer (Date Filed: 3/8/2007) re 92 MOTION to Intervene filed by John Grover,, Mederos Mederos,, Mark Watte,, 115 MOTION for Entry of Judgment under Rule 54(b) filed by Mike Johanns,, 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed by Sierra Club,, Trask Family Seeds,, Center for Food Safety,, Beyond Pesticides,, Cornucopia Institute,, Dakota Resource Council,, National Family Farm Coalition,, Western Organization of Resource Councils,, Geertson Seed Farms,, 86 MOTION to Intervene filed by Monsanto Company,, 88 MOTION to Intervene filed by Forage Genetics, Inc.,, Motions

		terminated:. (Court Reporter Kathy Powell.) (be, COURT STAFF) (Date Filed: 3/8/2007) (Entered: 03/08/2007)
		* * *
03/08/2007	134	Declaration of Mark H. McCaslin *(Third Declaration)* filed byMonsanto Company. (Tate, Holly) (Filed on 3/8/2007) (Entered: 03/08/2007)
03/09/2007	135	Reply Memorandum *Plaintiffs' Reply to Third Declaration of Mark McCaslin and Proposal for Briefing* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 3/9/2007) (Entered: 03/09/2007)
03/09/2007	137	TRANSCRIPT of Proceedings held on 1/19/07 before Judge Charles R. Breyer. Court Reporter: Katherine A. Powell. (mcl, COURT STAFF) (Filed on 3/9/2007) (Entered: 03/12/2007)
03/12/2007	136	PRELIMINARY INJUNCTION. Signed by Judge Charles R. Breyer on 3/12/2007.

(crblc1, COURT STAFF) (Filed on 3/12/2007) (Entered: 03/12/2007)

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03/23/2007	141	Memorandum in Opposition re 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed byMonsanto Company. (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	142	Declaration of Annette M. Kirk in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Attachments: # 1 Exhibits A - F)(Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	143	Declaration of Daniel H. Putnam in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	144	Declaration of Dan Undersander in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	145	Declaration of Kent J. Bradford in Support of 141 Memorandum in

		Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	146	Declaration of Larry R. Teuber in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	147	Declaration of Louis Meyer (Second Declaration) in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	148	Declaration of Growers in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	149	Declaration of Paulette Pierson (Second Declaration) in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s) 141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	150	Declaration of Mark McCaslin in Support of 141 Memorandum in Opposition filed byMonsanto Company. (Related document(s)

		141) (Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	151	MOTION to Strike 124 Declaration in Opposition,,, 97 Declaration in Support,, 94 Declaration in Support,, 121 Declaration in Opposition,, 125 Declaration in Opposition, filed by Monsanto Company. Motion Hearing set for 4/27/2007 11:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Exhibit A# 2 Proposed Order)(Tate, Holly) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	152	MEMORANDUM in Support *Re Permanent Relief* filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 # 2 # 3 # 4 # 5 # 6 # 7 # 8 # 9 # 10)(Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	153	EXHIBITS re 152 Memorandum in Support *Exhs 11 through 17* filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Exhibit # 2 # 3 # 4 # 5 # 6)(Related document(s) 152) (Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	154	EXHIBITS re 152 Memorandum in Support *Exhibit 18 Putnam*

		Testimony and Exhibits filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 # 2)(Related document(s) 152) (Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	155	EXHIBITS re 152 Memorandum in Support *Exhibits 19 through 21* filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 # 2)(Related document(s) 152) (Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	156	EXHIBITS re 152 Memorandum in Support *Exhibit 22 and 23* filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1)(Related document(s) 152) (Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	157	MOTION to Seal Document *Administrative Motion to File Documents Under Seal* filed by Forage Genetics, Inc.. (Attachments: # 1 Declaration# 2 Stipulation# 3 Proposed Order)(Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	158	MOTION for Leave to File *A Motion for Reconsideration of the Scope of the Preliminary*

		Injunction filed by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Proposed Order Proposed Order)(Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	159	MOTION for Reconsideration *of the Scope of The Preliminary Injunction* filed by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Proposed Order)(Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/23/2007	160	OBJECTIONS to *Plaintiffs' Declarations Filed In Support of 119 Plaintiffs' Opposition to Defendants' Motion to Approve APHIS' Proposed Judgment* by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Kays, David) (Filed on 3/23/2007) Modified on 3/26/2007 (mcl, COURT STAFF). (Entered: 03/23/2007)
03/23/2007	161	AFFIDAVIT re 159 MOTION for Reconsideration *of the Scope of The Preliminary Injunction*, 155 Exhibits, 158 MOTION for Leave to File *A Motion for Reconsideration of the Scope of the Preliminary Injunction*, 153 Exhibits,, 157 MOTION to Seal

		Document *Administrative Motion to File Documents Under Seal,* 160 Objection,, 152 Memorandum in Support, 154 Exhibits, 156 Exhibits *Attorney Signature Attestation for Declarations Filed In Support of Intervenors' Papers Filed on March 23, 2007* by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Kays, David) (Filed on 3/23/2007) (Entered: 03/23/2007)
03/26/2007	162	ORDER by Judge Charles R. Breyer granting 157 Motion to Seal Document (be, COURT STAFF) (Filed on 3/26/2007) (Entered: 03/26/2007)
03/26/2007	163	Direct Testimony of Timothy J. Nantell regarding permanent relief filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. *** **FILED UNDER SEAL** *** (mcl, COURT STAFF) (Filed on 3/26/2007) (Entered: 03/28/2007)
		* * *
04/06/2007	165	RESPONSE in Support *of 93 Plaintiffs Permanent Injunction, Response to Intervenors' Memorandum Regarding Permanent Relief* filed byBeyond Pesticides, Cornucopia Institute,

		Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Declaration of Albert Straus# 2 Declaration Ernest Johnson# 3 Declaration of Gary Zimmer# 4 Declaration of George Siemon# 5 Declaration of John Markegard# 6 Declaration of Larry Meyer# 7 Declaration of Lee McSherry# 8 Declaration of Mike Nichols# 9 Declaration of Tom Baxter)(Rostov, William) (Filed on 4/6/2007) Modified on 4/9/2007 (mcl, COURT STAFF). (Entered: 04/06/2007)
04/06/2007	166	Declaration in Support of 165 Response in Support,, *Declaration of Kevin Golden in Support of Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C)(Related

		document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	167	Declaration of Doug Gurian-Sherman in Support of 165 Response in Support,, *of Plaintiffs Permanent Injunction* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C# 4 Exhibit D# 5 Exhibit E# 6 Exhibit F# 7 Exhibit G# 8 Exhibit H# 9 Exhibit I# 10 Exhibit J# 11 Exhibit K# 12 Exhibit L# 13 Exhibit M# 14 Exhibit N# 15 Exhibit O)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	168	Declaration of Dr. Allison Snow in Support of 165 Response in Support,, *of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource

		Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	169	Declaration of Dr. Charles Benbrook in Support of 165 Response in Support,, *of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	170	Declaration of Dr. Clinton Shock in Support of 165 Response in Support,, *of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for

		Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	171	*** **SEE ENTRY BELOW 172 FOR ATTACHMENTS** *** Declaration of William Freese in Support of 165 Response in Support, *Supplemental Declaration in Support of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) Modified on 4/9/2007 (mcl, COURT STAFF). (Entered: 04/06/2007)
04/06/2007	172	Declaration of William Freese in Support of 165 Response in Support,, *[errata with Exhibits] Supplemental Declaration in Support of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western

		Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	173	Declaration of Jim Briggs in Support of 165 Response in Support,, *of Plaintiffs Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C# 4 Exhibit D)(Related document(s) 165) (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	174	MOTION to *Strike Directed Testimony Submitted by Intervenors Monsanto and Forage Genetics* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource

		Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. Motion Hearing set for 4/27/2007 11:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order)(Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	175	MEMORANDUM in Opposition *to Monsanto Company's Motion to Strike 151 filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order)(Rostov, William) (Filed on 4/6/2007) Modified on 4/9/2007 (mcl, COURT STAFF). (Entered: 04/06/2007)*
04/06/2007	176	Memorandum in Opposition *Plaintiffs Responses to Intervenor-Defendants Objections to Plaintiffs Declarations in Support of Motion for Permanent Injunction* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition,

		Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)
04/06/2007	177	Memorandum in Opposition *Plaintiffs Reponse to Intervenor-Defendants Objections to Plaintiffs Declarations* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 4/6/2007) (Entered: 04/06/2007)

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04/12/2007	179	CASE MANAGEMENT STATEMENT - *REQUEST FOR CASE MANAGEMENT CONFERENCE* filed by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Kays, David) (Filed on 4/12/2007) (Entered: 04/12/2007)
04/13/2007	180	Memorandum in Opposition *JOINT OPPOSITION OF INTERVENOR-*

		DEFENDANTS TO PLAINTIFFS' MOTION TO STRIKE "DIRECTED TESTIMONY" 174 filed byForage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Kays, David) (Filed on 4/13/2007) Modified on 4/17/2007 (mcl, COURT STAFF). (Entered: 04/13/2007)
04/13/2007	181	*Plaintiffs' Oppostion to Intervenors' Request for Case Management Conference* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 4/13/2007) Modified on 4/17/2007 (mcl, COURT STAFF). (Entered: 04/13/2007)
04/13/2007	182	Reply to Opposition re 151 MOTION to Strike 124 Declaration in Opposition,,, 97 Declaration in Support,, 94 Declaration in Support,, 121 Declaration in Opposition,, 125 Declaration in Opposition,, 175 Memorandum in Opposition, filed byMonsanto Company. (Tate, Holly) (Filed on 4/13/2007)

		(Entered: 04/13/2007)
04/16/2007	183	TRANSCRIPT of Proceedings held on 3/8/07 before Judge Charles R. Breyer. Court Reporter: Katherine A. Powell. (mcl, COURT STAFF) (Filed on 4/16/2007) (Entered: 04/17/2007)
04/17/2007	184	OBJECTIONS to *PLAINTIFFS' DECLARATIONS FILED IN SUPPORT OF 93 PLAINTIFFS' PERMANENT INJUNCTION* by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Kays, David) (Filed on 4/17/2007) Modified on 4/19/2007 (mcl, COURT STAFF). (Entered: 04/17/2007)
04/20/2007	185	MOTION for Leave to File *Supplementary Material [L.R. 7-3(d)]* filed by Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. Motion Hearing set for 4/27/2007 11:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Exhibit 1 Rebuttal Testimony of Mark McCaslin# 2 Exhibit 2 Rebuttal Testimony of Sharie Fitzpatrick# 3 Exhibit 3 Rebuttal Declaration of Timothy J. Nantell# 4 Exhibit 4 Response of Timothy J. Nantell to Plaintiffs' Request for New Relief# 5 Exhibit 5 Rebuttal Testimony of

		Bob Hammon# 6 Proposed Order Granting Motion for Leave to File Supplementary Material)(Kays, David) (Filed on 4/20/2007) (Entered: 04/20/2007)
04/20/2007	186	MOTION for Leave to File *Surreply on Proposed Permanent Injunction* filed by Monsanto Company. Motion Hearing set for 4/27/2007 11:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order # 2 Surreply on Proposed Permanent Injunction# 3 Ex. 1 to Surreply - Hammon Rebuttal Testimony# 4 Ex. 2 to Surreply - Third Pierson Declaration# 5 Ex. 3 to Surreply - McCaslin Rebuttal Testimony# 6 Ex. 4 to Surreply - Nantell Rebuttal Declaration# 7 Ex. 5 to Surreply - Fitzpatrick Rebuttal Testimony# 8 Ex. 6 to Surreply - Nantell Response to Request for New Relief)(Tate, Holly) (Filed on 4/20/2007) (Entered: 04/20/2007)
04/20/2007	187	OBJECTIONS to re 169 Declaration in Support,, 167 Declaration in Support,,, 165 Response in Support,,, *(Plaintiff's Declarations in Support of Permanent Injunction)* by Monsanto Company. (Tate, Holly) (Filed on

		4/20/2007) (Entered: 04/20/2007)
04/23/2007	188	ORDER re: request for cmc. Signed by Judge Charles R. Breyer on 4/23/2007. (crblc1, COURT STAFF) (Filed on 4/23/2007) (Entered: 04/23/2007)
04/23/2007	189	MOTION for Leave to File *Amicus Curiae Brief* filed by AMERICAN FARM BUREAU FEDERATION. Motion Hearing set for 4/27/2007 11:00 AM in Courtroom 8, 19th Floor, San Francisco. (Gupta, Shirish) (Filed on 4/23/2007) (Entered: 04/23/2007)
04/24/2007	190	MEMORANDUM in Opposition *to 185 Intervenors' Motion for Leave to File Supplemental Material* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Golden, Kevin) (Filed on 4/24/2007) Modified on 4/26/2007 (mcl, COURT STAFF). (Entered: 04/24/2007)
04/24/2007	191	RESPONSE to 184 Intervenors Forage Genetics et al.'s Objections to Plaintiffs' Declarations Filed in Support of

		Plaintiffs' Permanent Injunction by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Golden, Kevin) (Filed on 4/24/2007) Modified on 4/26/2007 (mcl, COURT STAFF). (Entered: 04/24/2007)
04/24/2007	192	RESPONSE to 187 Intervenor Monsanto's Objections to Plaintiffs' Declarations Filed in Support of Plaintiffs' Permanent Injunction by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Golden, Kevin) (Filed on 4/24/2007) Modified on 4/26/2007 (mcl, COURT STAFF). (Entered: 04/24/2007)
04/24/2007	193	MEMORANDUM in Opposition *to 189 American Farm Bureau's Motion to File Amicus Curiae Brief* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National

		Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Golden, Kevin) (Filed on 4/24/2007) Modified on 4/26/2007 (mcl, COURT STAFF). (Entered: 04/24/2007)
		* * *
04/25/2007	197	Reply to Opposition re 190 Memorandum in Opposition, *(to Motion for Leave to File Surreply)* filed byMonsanto Company. (Tate, Holly) (Filed on 4/25/2007) (Entered: 04/25/2007)
04/27/2007	198	Minute Entry: Motion Hearing held on 4/27/2007 before Charles R. Breyer (Date Filed: 4/27/2007) re 151 MOTION to Strike 124 Declaration in Opposition,,, 97 Declaration in Support,, 94 Declaration in Support,, 121 Declaration in Opposition,, 125 Declaration in Opposition, filed by Monsanto Company,, 93 MOTION for Permanent Injunction , *Final Relief and Entry of Judgment* filed by Sierra Club,, Trask Family Seeds,, Center for Food Safety,, Beyond Pesticides,, Cornucopia Institute,, Dakota Resource Council,, National

		Family Farm Coalition,, Western Organization of Resource Councils,, Geertson Seed Farms,, 174 MOTION to Strike *Directed Testimony Submitted by Intervenors Monsanto and Forage Genetics* filed by Sierra Club,, Trask Family Seeds,, Center for Food Safety,, Beyond Pesticides,, Cornucopia Institute,, Dakota Resource Council,, National Family Farm Coalition,, Western Organization of Resource Councils,, Geertson Seed Farms,, 186 MOTION for Leave to File Surreply on *Proposed Permanent Injunction* filed by Monsanto Company,, 189 MOTION for Leave to File *Amicus Curiae Brief* filed by AMERICAN FARM BUREAU FEDERATION,. (Court Reporter Joan Columbini.) (be, COURT STAFF) (Date Filed: 4/27/2007) (Entered: 04/27/2007)
05/03/2007	199	MEMORANDUM AND ORDER re: PERMANENT INJUNCTION. Signed by Judge Charles R. Breyer on May 3, 2007. (crblc2, COURT STAFF) (Filed on 5/3/2007) (Entered: 05/03/2007)
05/03/2007	200	JUDGMENT in favor of plaintiffs against defendants. Signed by Judge Charles R. Breyer on

		5/3/2007. (crblc1, COURT STAFF) (Filed on 5/3/2007) (Entered: 05/03/2007)
05/10/2007	201	MOTION for Extension of Time to File *Claim for Costs* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Declaration)(Golden, Kevin) (Filed on 5/10/2007) (Entered: 05/10/2007)
05/11/2007	202	ORDER by Judge Charles R. Breyer granting 201 Motion for Extension of Time to File (be, COURT STAFF) (Filed on 5/11/2007) (Entered: 05/11/2007)
		* * *
05/16/2007	204	TRANSCRIPT of Proceedings held on 4/27/07 before Judge Charles R. Breyer. Court Reporter: Joan Marie Columbini. (mcl, COURT STAFF) (Filed on 5/16/2007) (Entered: 05/16/2007)
05/17/2007	205	MOTION to Alter Judgment filed by Mike Johanns. Motion Hearing set for 6/22/2007 10:00 AM. (Attachments: # 1 Affidavit)(Page, Gregory) (Filed

		on 5/17/2007) (Entered: 05/17/2007)
05/17/2007	206	MOTION to Amend/Correct 200 Judgment filed by Monsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. Motion Hearing set for 6/22/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1 Proposed Order)(Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
05/17/2007	207	Declaration of Scott Baucum in Support of 206 MOTION to Amend/Correct 200 Judgment filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 206) (Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
05/17/2007	208	Declaration of Paulette Pierson in Support of 206 MOTION to Amend/Correct 200 Judgment filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 206) (Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
05/17/2007	209	Declaration of Mark McCaslin in Support of 206 MOTION to Amend/Correct 200 Judgment

		filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 206) (Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
05/17/2007	210	Declaration of Dr. Neil Hoffman *in Support of 205 Defendants' Rule 59 Motion to Alter or Amend* filed byMike Johanns. (Page, Gregory) (Filed on 5/17/2007) Modified on 5/18/2007 (mcl, COURT STAFF). (Entered: 05/17/2007)
05/17/2007	211	Declaration of Rachel Lattimore in Support of 206 MOTION to Amend/Correct 200 Judgment filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Exhibit A - Part 1# 2 Exhibit A - Part 2# 3 Exhibit B# 4 Exhibit C# 5 Exhibit D# 6 Exhibit E# 7 Exhibit F# 8 Exhibit G# 9 Exhibit H# 10 Exhibit I# 11 Exhibit J)(Related document(s) 206) (Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
		* * *
05/17/2007	213	Declaration of Philip Perry in Support of 212 MOTION to Shorten Time *for Intervenor-*

		Defendants' Motion to Amend or Clarify the Court's May 3, 2007, Judgment or, in the Alternative, to Stay Portions of the Judgment filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 212) (Tate, Holly) (Filed on 5/17/2007) (Entered: 05/17/2007)
05/21/2007	214	Memorandum in Opposition re 212 MOTION to Shorten Time *for Intervenor-Defendants' Motion to Amend or Clarify the Court's May 3, 2007, Judgment or, in the Alternative, to Stay Portions of the Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order)(Rostov, William) (Filed on 5/21/2007) (Entered: 05/21/2007)

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06/01/2007	217	Memorandum in Opposition re 205 MOTION to Alter Judgment, 206 MOTION to Amend/Correct 200 Judgment filed byBeyond

		Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order # 2 Plaintiffs' Objections to Defendants' Declarations Filed in Support of Defendants' Motions to Amend the Judgment)(Rostov, William) (Filed on 6/1/2007) (Entered: 06/01/2007)
06/01/2007	218	Declaration of Jim Briggs in Support of 217 Memorandum in Opposition,, *to Defendants' Motion to Amend the Court's May 3, 2007 Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 217) (Rostov, William) (Filed on 6/1/2007) (Entered: 06/01/2007)
		* * *
06/01/2007	220	Declaration of Britt Bailey in

		Support of 217 Memorandum in Opposition,, *to Defendants' Motion to Amend the Court's May 3, 2007 Judgment* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B)(Related document(s) 217) (Rostov, William) (Filed on 6/1/2007) (Entered: 06/01/2007)
06/01/2007	221	Declaration of Mark McAfee in Support of 217 Memorandum in Opposition,, *to Defendants' Motion to Amend the Court's May 3, 2007 Judgment CORRECTION OF DOCKET # 219* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 217) (Rostov, William) (Filed on 6/1/2007) (Entered: 06/01/2007)

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06/07/2007	223	STIPULATION AND ORDER taking the motion for costs and fees off the 08/08/07 calendar. Signed by Judge Charles R. Breyer on 06/07/07. (rbe, COURT STAFF) (Filed on 6/7/2007) (Entered: 06/07/2007)
06/08/2007	224	Reply to Opposition *to 205 Defendants' Rule 59 Motion* filed byMike Johanns. (Page, Gregory) (Filed on 6/8/2007) Modified on 6/11/2007 (mcl, COURT STAFF). (Entered: 06/08/2007)
06/08/2007	225	Reply to Opposition re 206 MOTION to Amend/Correct 200 Judgment MOTION to Amend/Correct 200 Judgment filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Attachments: # 1 Proposed Order)(Tate, Holly) (Filed on 6/8/2007) (Entered: 06/08/2007)
06/08/2007	226	Declaration of Robert A. Ihrig in Support of 225 Reply to Opposition, filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 225) (Tate, Holly) (Filed on 6/8/2007) (Entered:

		06/08/2007)
06/08/2007	227	Declaration of Scott Baucum in Support of 225 Reply to Opposition, filed byMonsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Related document(s) 225) (Tate, Holly) (Filed on 6/8/2007) (Entered: 06/08/2007)
06/08/2007	228	RESPONSE to re 217 Memorandum in Opposition,, *(Response to Plaintiffs' Objections To Defendants' Declarations)* by Monsanto Company, Forage Genetics, Inc., John Grover, Mederos Mederos, Mark Watte. (Tate, Holly) (Filed on 6/8/2007) (Entered: 06/08/2007)
		* * *
06/22/2007	231	Minute Entry: Motion Hearing held on 6/22/2007 before Charles R. Breyer (Date Filed: 6/22/2007) re 212 MOTION to Shorten Time *for Intervenor-Defendants' Motion to Amend or Clarify the Court's May 3, 2007, Judgment or, in the Alternative, to Stay Portions of the Judgment* filed by John Grover, Mark Watte, Monsanto Company, Mederos Mederos, Forage Genetics, Inc., 206 MOTION to Amend/Correct

		200 Judgment MOTION to Amend/Correct 200 Judgment filed by John Grover, Mark Watte, Monsanto Company, Mederos Mederos, Forage Genetics, Inc., 205 MOTION to Alter Judgment filed by Mike Johanns. (Court Reporter Juanita Gonzalez.) (be, COURT STAFF) (Date Filed: 6/22/2007) (Entered: 06/22/2007)
		* * *
06/26/2007	233	ORDER granting motions to amend judgment. Signed by Judge Charles R. Breyer on 6/25/2007. (crblc1, COURT STAFF) (Filed on 6/26/2007) (Entered: 06/26/2007)
07/02/2007	234	STATUS REPORT *(Joint)* by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Monsanto Company, Mike Johanns, Forage Genetics, Inc., Ron Dehaven, John Grover, Mederos Mederos, Mark Watte, Steve Johnson, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Tate, Holly) (Filed on 7/2/2007) (Entered: 07/02/2007)

07/06/2007	235	STIPULATION re 233 Order *FOR LEAVE TO FILE AN AMENDED JUDGMENT ON OR BEFORE JULY 13, 2007* by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Monsanto Company, Mike Johanns, Forage Genetics, Inc., Ron Dehaven, John Grover, Mederos Mederos, Mark Watte, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 7/6/2007) (Entered: 07/06/2007)
07/10/2007	236	ORDER re 235 Stipulation, filed by Mederos Mederos, Dakota Resource Council, Sierra Club, Geertson Seed Farms, Western Organization of Resource Councils, Mike Johanns, Mark Watte, Ron Dehaven, Forage Genetics, Inc., Trask Family Seeds, Center for Food Safety, Monsanto Company, Beyond Pesticides, John Grover, Cornucopia Institute, National Family Farm Coalition Amended Pleadings due by 7/13/2007.. Signed by Judge Charles R. Breyer on 7/09/07. (be, COURT STAFF) (Filed on 7/10/2007)

		(Entered: 07/10/2007)
07/13/2007	237	MOTION to Approve Consent Judgment filed by Mike Johanns. (Attachments: # 1 Proposed Order)(Page, Gregory) (Filed on 7/13/2007) (Entered: 07/13/2007)
07/23/2007	238	AMENDED JUDGMENT by Judge Charles R. Breyer granting 237 Motion to Approve Consent Judgment (be, COURT STAFF) (Filed on 7/23/2007) (Entered: 07/23/2007)
07/25/2007	239	TRANSCRIPT of Proceedings held on 6/22/07 before Judge Charles R. Breyer. Court Reporter: Juanita Gonzalez. (mcl, COURT STAFF) (Filed on 7/25/2007) (Entered: 07/26/2007)
08/13/2007	240	NOTICE OF APPEAL as to 83 Order on Motion for Summary Judgment, 199 Order, 238 Order on Motion to Approve Consent Judgment, 200 Judgment by Monsanto Company. Filing fee $ 455, receipt number 3461100939. (mcl, COURT STAFF) (Filed on 8/13/2007) (Entered: 08/14/2007)
08/13/2007		Received Representation Statement by Monsanto Company. (mcl, COURT STAFF) (Entered: 08/14/2007)
08/13/2007		Received Civil Appeals Docketing Statement by Monsanto Company. (mcl, COURT STAFF)

		(Entered: 08/14/2007)
08/14/2007		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals. (mcl, COURT STAFF) (Entered: 08/14/2007)
		* * *
08/16/2007	241	NOTICE OF APPEAL as to 238 Order on Motion to Approve Consent Judgment by Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. Filing fee $ 455, receipt number 34611009499. (sv, COURT STAFF) (Filed on 8/16/2007) (Entered: 08/17/2007)
08/16/2007	242	Received Received Representation Statement by Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (sv, COURT STAFF) (Filed on 8/16/2007) (Entered: 08/17/2007)
08/16/2007	243	Received Civil Appeals Docketing Statement by Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (sv, COURT STAFF) (Filed on 8/16/2007) (Entered: 08/17/2007)
08/20/2007		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re 241 Notice of Appeal (sv, COURT STAFF) (Filed on 8/20/2007) (Entered: 08/20/2007)

* * *

08/20/2007	244	USCA Scheduling Order as to 240 Notice of Appeal, filed by Monsanto Company. (sv, COURT STAFF) (Filed on 8/20/2007) Modified on 8/21/2007 (sv, COURT STAFF). (Entered: 08/21/2007)
08/20/2007	245	USCA Case Number 07-16458 U.S. Court of Appeals for the Ninth Circuit for 240 Notice of Appeal, filed by Monsanto Company. (sv, COURT STAFF) (Filed on 8/20/2007) Modified on 8/21/2007 (sv, COURT STAFF). (Entered: 08/21/2007)
08/22/2007	246	DESIGNATION of Record on Appeal by Monsanto Company re 240 Notice of Appeal, (Tate, Holly) (Filed on 8/22/2007) (Entered: 08/22/2007)
08/24/2007	247	TRANSCRIPT DESIGNATION *and ORDERING FORM* by Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte for proceedings held on 06/30/06; 01/19/07; 03/05/07; 03/08/07; 04/27/07; 06/22/07 before Judge Charles R. Breyer.. (Luemers, Martha) (Filed on 8/24/2007) (Entered: 08/24/2007)
08/27/2007	248	USCA Scheduling Order as to 241 Notice of Appeal filed by John

		Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc.. (sv, COURT STAFF) (Filed on 8/27/2007) (Entered: 08/27/2007)
		* * *
08/27/2007	250	STATUS REPORT by Monsanto Company, Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (Tate, Holly) (Filed on 8/27/2007) (Entered: 08/27/2007)
08/27/2007	251	Declaration of Scott Baucum in Support of 250 Status Report filed byMonsanto Company, Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (Related document(s) 250) (Tate, Holly) (Filed on 8/27/2007) (Entered: 08/27/2007)
08/29/2007	252	TRANSCRIPT of Proceedings held on 6/30/06 before Judge Charles R. Breyer. Court Reporter: Katherine Wyatt. (sv, COURT STAFF) (Filed on 8/29/2007) Modified on 8/30/2007 (sv, COURT STAFF). (Entered: 08/30/2007)
09/12/2007	253	ORDER of USCA as to 240 Notice of Appeal, filed by Monsanto Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. The court

		sua sponte consolidates nos. 07-16458 and 07-16492. Intervenor-Appellant Monsanto Company's opposed motion for expedition is denied. (mcl, COURT STAFF) (Filed on 9/12/2007) (Entered: 09/13/2007)
09/18/2007	254	NOTICE by Mike Johanns *Notice of Appeal* (Page, Gregory) (Filed on 9/18/2007) (Entered: 09/18/2007)
09/19/2007		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re 254 Appeal. (mcl, COURT STAFF) (Entered: 09/19/2007)
09/19/2007		Copy of Notice of Appeal and Docket sheet mailed to all counsel re 254 Appeal. (mcl, COURT STAFF) (Entered: 09/19/2007)
10/04/2007	255	USCA Scheduling Order (USCA # 07-16725) as to 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. (mcl, COURT STAFF) (Filed on 10/4/2007) (Entered: 10/04/2007)
10/10/2007	256	TRANSCRIPT of Proceedings held on 3/5/07 before Judge Charles R. Breyer. Court Reporter: James Yeomans. (mcl, COURT STAFF) (Filed on 10/10/2007) (Entered: 10/11/2007)
10/11/2007	257	STATUS REPORT by Monsanto

		Company, Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (Tate, Holly) (Filed on 10/11/2007) (Entered: 10/11/2007)
10/11/2007	258	Declaration of Scott Baucum in Support of 257 Status Report filed byMonsanto Company, Forage Genetics, Inc., John Grover, Daniel Mederos, Mark Watte. (Related document(s) 257) (Tate, Holly) (Filed on 10/11/2007) (Entered: 10/11/2007)
10/19/2007	259	ORDER of USCA as to 240 Notice of Appeal, filed by Monsanto Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. Intervenor-Appellant Monsanto Company's opposed motion for reconsideration is granted in part and denied in part. (mcl, COURT STAFF) (Filed on 10/19/2007) (Entered: 10/19/2007)
10/19/2007	260	MOTION for Attorney Fees *and Costs* filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. Motion Hearing set

		for 11/30/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Golden, Kevin) (Filed on 10/19/2007) (Entered: 10/19/2007)
10/19/2007	261	MEMORANDUM in Support re 260 MOTION for Attorney Fees *and Costs* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order # 2 Declaration# 3 Declaration# 4 # 5 Declaration# 6 Declaration# 7 Declaration# 8 Declaration# 9 Declaration# 10 Declaration# 11 Declaration# 12 Declaration# 13 Declaration# 14 Declaration# 15 Declaration# 16 Declaration)(Related document(s) 260) (Golden, Kevin) (Filed on 10/19/2007) (Entered: 10/19/2007)
10/19/2007	262	Declaration of William B. Rostov in Support of 261 Memorandum in Support,, *Plaintiffs' Motion for Fees and Costs* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of

		Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A# 2 Exhibit B# 3 Exhibit C# 4 Exhibit D)(Related document(s) 261) (Golden, Kevin) (Filed on 10/19/2007) Modified on 10/22/2007 (mcl, COURT STAFF). (Entered: 10/19/2007)
10/19/2007	263	Declaration of Kevin Golden in Support of 261 Memorandum in Support,, *Plaintiffs' Motion for Fees and Costs* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 261) (Golden, Kevin) (Filed on 10/19/2007) Modified on 10/22/2007 (mcl, COURT STAFF). (Entered: 10/19/2007)
11/07/2007	264	MOTION to Stay *Plaintiffs' Fee Petition Pending a Final Decision on the Merits* filed by Mike Johanns. Motion Hearing set for 12/12/2007 10:00 AM in Courtroom 8, 19th Floor, San Francisco. (Attachments: # 1

		Proposed Order)(Page, Gregory) (Filed on 11/7/2007) (Entered: 11/07/2007)
		* * *
11/14/2007	266	Memorandum in Opposition *To 265 Defendants' Motion to Shorten Hearing Date For Their Motion to Stay And Suspend Hearing Date For Plaintiffs' Attorneys' Fee Petition* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Rostov Declaration# 2 Proposed Order)(Golden, Kevin) (Filed on 11/14/2007) Modified on 11/15/2007 (mcl, COURT STAFF). (Entered: 11/14/2007)
11/16/2007	267	Reply Memorandum *to Defendants' Failure to Oppose 260 Plaintiffs' Motion for Award of Attorneys' Fees And Costs* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed

		Farms, Center for Food Safety. (Golden, Kevin) (Filed on 11/16/2007) Modified on 11/19/2007 (mcl, COURT STAFF). (Entered: 11/16/2007)
11/19/2007	268	SCHEDULING ORDER by Judge Charles R. Breyer (crblc1, COURT STAFF) (Filed on 11/19/2007) (Entered: 11/19/2007)
11/19/2007		Set/Reset Deadlines as to 260 MOTION for Attorney Fees *and Costs*, 264 MOTION to *Stay Plaintiffs' Fee Petition Pending a Final Decision on the Merits*. Responses due by 11/30/2007. Replies due by 12/7/2007. Motion Hearing set for 12/14/2007 10:00 AM. (be, COURT STAFF) (Filed on 11/19/2007) (Entered: 11/20/2007)
11/30/2007	269	Memorandum in Opposition *to 264 Defendants' Motion to Stay Fee Petition Pending A Final Decision On The Merits* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order)(Golden, Kevin) (Filed on 11/30/2007) Modified on 12/3/2007

		(mcl, COURT STAFF). (Entered: 11/30/2007)
12/03/2007	270	Memorandum in Opposition *to 260 Plaintiffs' Motion for Award of Attorneys' Fees and Costs* filed byMike Johanns. (Attachments: # 1 Affidavit Gregory Daniel Page)(Page, Gregory) (Filed on 12/3/2007) Modified on 12/4/2007 (mcl, COURT STAFF). (Entered: 12/03/2007)
12/07/2007	271	Reply to Opposition *to 264 Defendants' Motion to Stay Plaintiffs' Fee Petition Pending a Final Decision on the Merits* filed byMike Johanns. (Page, Gregory) (Filed on 12/7/2007) Modified on 12/10/2007 (mcl, COURT STAFF). (Entered: 12/07/2007)
12/07/2007	272	Reply to Opposition re 260 MOTION for Attorney Fees *and Costs* filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Rostov, William) (Filed on 12/7/2007) (Entered: 12/07/2007)
12/07/2007	273	Declaration of Kevin Golden in Support of 272 Reply to Opposition, filed byBeyond

		Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A)(Related document(s) 272) (Rostov, William) (Filed on 12/7/2007) (Entered: 12/07/2007)
12/07/2007	274	Declaration of William B. Rostov in Support of 272 Reply to Opposition, filed byBeyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Related document(s) 272) (Rostov, William) (Filed on 12/7/2007) (Entered: 12/07/2007)
12/14/2007	275	Minute Entry: Motion Hearing held on 12/14/2007 before Charles R. Breyer. D's Motion to Stay is GRANTED. P's Motion for Award of Attorneys' Fees and Costs is DEFERRED. (Court Reporter Joan Columbini.) (fj, COURT STAFF) (Date Filed:

		12/14/2007) (Entered: 12/14/2007)
01/23/2008	276	MOTION to Relate Case *(Civ. L.R. 3-12 & 7-11)* filed by Center for Food Safety. (Attachments: # 1 Proposed Order)(Loarie, Gregory) (Filed on 1/23/2008) (Entered: 01/23/2008)
01/23/2008	277	CERTIFICATE OF SERVICE by Center for Food Safety re 276 MOTION to Relate Case *(Civ. L.R. 3-12 & 7-11)* (Loarie, Gregory) (Filed on 1/23/2008) (Entered: 01/23/2008)
01/25/2008	278	Memorandum in Opposition re 276 MOTION to Relate Case *(Civ. L.R. 3-12 & 7-11)* filed byMonsanto Company. (Attachments: # 1 Proposed Order)(Tate, Holly) (Filed on 1/25/2008) (Entered: 01/25/2008)
		* * *
01/28/2008	280	Memorandum in Opposition re 276 MOTION to Relate Case *(Civ. L.R. 3-12 & 7-11) Federal Defendants' Response* filed byMike Johanns, Ron Dehaven, Steve Johnson. (Attachments: # 1 Proposed Order)(Caramanian, Lori) (Filed on 1/28/2008) (Entered: 01/28/2008)
02/01/2008	281	ORDER by Judge Charles R. Breyer denying 276 Motion to Relate Case (be, COURT

		STAFF) (Filed on 2/1/2008) (Entered: 02/01/2008)
		* * *
04/29/2008	283	Certified and Transmitted Record on Appeal to US Court of Appeals re 240 Notice of Appeal. (mcl, COURT STAFF) (Filed on 4/29/2008) (Entered: 04/29/2008)
09/08/2008	284	USCA 0PINION as to 240 Notice of Appeal, filed by Monsanto Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. (slh, COURT STAFF) (Filed on 9/8/2008) (Entered: 09/08/2008)
		* * *
05/21/2009	286	MOTION for leave to appear in Pro Hac Vice (George Andreas Kimbrell) (Filing fee $ 210, receipt number 34611032408.) filed by Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, Western Organization of Resource Councils, Trask Family Seeds, Geertson Seed Farms, Center for Food Safety. (Attachments: # 1 Proposed Order)(mcl, COURT STAFF) (Filed on 5/21/2009) (Entered:

		05/21/2009)
06/01/2009	287	ORDER by Judge Charles R. Breyer granting 286 Motion for Pro Hac Vice (be, COURT STAFF) (Filed on 6/1/2009) (Entered: 06/01/2009)
		* * *
06/24/2009	289	ORDER AND AMENDED OPINION of USCA as to 240 Notice of Appeal, filed by Monsanto Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. The district court's order is affirmed. (mcl, COURT STAFF) (Filed on 6/24/2009) (Entered: 06/24/2009)
07/15/2009	290	MANDATE of USCA as to 240 Notice of Appeal, filed by Monsanto Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. (mcl, COURT STAFF) (Filed on 7/15/2009) (Entered: 07/15/2009)
07/15/2009	291	CLERKS Letter Spreading Mandate to Counsel re 290 . (mcl, COURT STAFF) (Filed on 7/15/2009) (Entered: 07/15/2009)
09/23/2009	292	ORDER of U.S. Supreme Court (USCA case nos. 07-16458, 07-16492, 07-16725) as to 240 Notice of Appeal, filed by Monsanto

Company, 241 Notice of Appeal filed by John Grover, Mark Watte, Daniel Mederos, Forage Genetics, Inc. The application for an extension of time to file a petition for a writ of certiorari has been extended to & including 10/22/09. (mcl, COURT STAFF) (Entered: 09/23/2009)

JA-101

[Logos Omitted]
MONSANTO Forage Genetics

Addendum 1

Petition for Determination of Nonregulated Status:
Roundup Ready® Alfalfa (*Medicago sativa* L.)
Events J101 and J163

USDA Petition Number: 04-110-01p
Monsanto Number: 04-AL-116U

OECD Unique Identifiers:
Event J101 - MON- ØØ1 Ø1-8
Event J163 - MON- ØØ163-7

Addendum 1 to Petition for Determination of Nonregulated Status: Roundup Ready Alfalfa (*Aledicago sativa* L.) Events J101 and J163

PART ONE:

Request from USDA: Please submit information on the likelihood that RR alfalfa seed will be used for sprouting and then consumed by humans.

Response: Information on the safety of Roundup Ready alfalfa has been submitted to the U.S. Food and Drug Administration (FDA BNF# 0084) and is currently being evaluated. FDA has previously assessed the safety of the CP4 EPSPS protein that is present in other Roundup Ready crops. In addition, EPA has granted an exemption from the requirement for a tolerance for the CP4 EPSPS protein [FR 61(150): (40338)]. Given the safety of the introduced protein and the substantial equivalence of harvested material, we have concluded that Roundup Ready alfalfa is as safe and nutritious as conventional alfalfa for food and feed uses. This would include the potential use of Roundup Ready alfalfa seed for production of sprouts. However, the likelihood that the trait would be intentionally used for the production of sprouts is low for the reasons given below.

All Roundup Ready alfalfa seed will be produced under production contracts and field management practices that will preclude the legal sale of the seed for food use. Under the terms of the production contract, the seed will be produced exclusively for field planting stock purposes with all seed production (for the foreseeable future) occurring exclusively in the United States. Only seed producers that are trained, licensed and

contracted to produce Roundup Ready alfalfa seed will be authorized to do so. As described in Section F. of USDA petition number 04-110-01P, forage producers who purchase Roundup Ready alfalfa seed will be required to sign a grower agreement that expressly prohibits the production of seed. Roundup Ready alfalfa seed will be commercially available as registered alfalfa varieties that will be clearly identified as a Roundup Ready variety on each seed bag, seed tag and on the purchase agreement (limited use license). Alfalfa seeds for planting purposes are commonly coated with seed treatments as a means to enhance stand establishment (Brick, 2002) or to uniquely identify certain proprietary varieties. All Roundup Ready alfalfa seed will be pre-treated with a colored coating that will contain bacterial (*Sinorhizobium meliloti*) inoculant to promote nodulation and/or a fungicide such as metalaxyl for control of seedling damping off fungi. Because treated seeds and seed produced for planting purposes should not be used for sprouting purposes (DeWaal, 1998; Oregon State University, 2004), the coating applied to Roundup Ready alfalfa seed along with packaging in labeled seed bags will uniquely identify seed that contains the trait, and preclude its use as a starting material for the production of alfalfa sprouts.

The vast majority of alfalfa seed that is produced in the U.S. is for planting purposes with a relatively small amount (estimated to be approximately 7%) used for the production of sprouts (Bass et al., 1988). A considerable amount of alfalfa seed is also imported from outside of the U.S. specifically for sprout production (FDA, 1999). Alfalfa sprouts are the most

common form of green sprouts available to consumers. In 1998 the total U.S. market for all types of sprouts was valued at approximately $25 million with over 400 growers producing 300,000 tons of sprouts annually (Kurtweil, 1999). Outbreaks of food-borne illness associated with sprouts containing the microbial pathogens *Salmonella* spp., *Escherichia coli* O157:H7 or *Listeria monocytogenes* have resulted in greater scrutiny of seed production practices in recent years and heightened the awareness of seed sources used for sprouting (FDA, 1999; CFIA, 2001). Seed have been identified as the primary source of these microbial contaminants (Puohiniemi et al., 1991; CDC, 1997; Mahon et al., 1997). Therefore, the sprouting industry endorses the use of certified sprouting seed to avoid these outbreaks (International Specialty Supply, 2004). Criteria evaluated for certification include seed production practices such as field history, pesticide/herbicide use and origin of seed. While it is not known how widely certified seed are used by the industry, according to the U.S. FDA, approximately 83% of sprout manufacturers surveyed reported using traceable seed sources, thus confirming that the industry is knowledgeable of the source of seeds used for sprout production (FDA, 1999).

Roundup Ready alfalfa will be marketed only when a consultation with FDA has been completed allowing for food and feed use of the product. It is not the intention of Monsanto or FGI to introduce Roundup Ready alfalfa for sprout seed production. It is unlikely that sprout seed producers and sprout producers will be impacted by the introduction of Roundup Ready alfalfa because multiple measures will be implemented by

both companies to avoid this use. These measures include, grower agreements and seed production contracts specifically limiting use of the crop for forage and seed for planting purposes, respectively, and colored seed inoculants/treatment and seed packaging clearly identifying the material as Roundup Ready alfalfa seed. Sprout producers and sprout seed producers purchasing seed will be able to avoid Roundup Ready alfalfa seed because of the colorant, seed bag label and mandatory grower agreement. Sprout seed producers who plant conventional alfalfa seed will be able to avoid the trait through appropriate isolation of their seed production fields from other seed production fields. Furthermore, systems are in place in the spouting industry to help maintain the identity and suitability of sprouting seed, including seed certification. In combination, these systems will effectively limit the presence of Roundup Ready alfalfa in seed for sprouting purposes.

References, Part One

Bass, L.N., Gunn, C.R., Hesterman, O.B., and Roos, E.E. 1988. Seed physiology, seedling performance, and seed sprouting. P. 961-979. *In* Hanson, A.A., Barnes, D.K., and Hill Jr., R.R. (ed.) Alfalfa and Alfalfa Improvement. ASA-CSSA-SSSA, Madison, Wisconsin. 1084 pp.

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eating alfalfa sprouts - Michigan and Virginia, June-July 1997. Morbid. Mortal. Weekly Rep. 46: 741-744.

CFIA. 2001. Canadian Food Inspection Agency. Draft code of practice for hygienic production of sprouted seeds. http://www.inspection.gc.ca/english/plaveg/fresh/sprointe.shtml [accessed 9/2004].

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FDA. 1999. Microbiological Safety Evaluations and Recommendations on Sprouted Seeds. U.S. Food and Drug Administration. National Advisory Committee on Microbiological Criteria for Food. http://vm.cfsan.fda.gov/~mow/sprouts2.html [accessed 9/2004]

International Specialty Supply, web site. http://www.sproutnet.com/seed certificate.htm [accessed, 8/2004]

Kurtweil P. 1999. Questions keep sprouting about sprouts. FDA Consumer News; 33: 18-22. http://www.fda.gov/fdac/features/1999/199_tsprt.html [accessed 9/2004]

Mahon, B.E., A. Ponka, W. Hall, K. Komatsu, L. Beuchat, S. Shiflett, A. Siitonen, G. Cage, M. Lambert, P. Hayes, N. Bean, P. Griffin, and L. Slutsker. 1997. An international outbreak of *Salmonella* infections caused by alfalfa sprouts grown from contaminated seed. J. Infect. Dis. 175:876-882.

Oregon State University. 2004. Commercial Vegetable Production Guides; Sprout Production. http://oregonstate.edu/Dept/NWREC/beansprt.html [accessed 9/2004]

Puohiniemi, R., T. Heiskanen, and A. Siitonen. 1997. Molecular epidemiology of two international sprout-borne *Salmonella* outbreaks. J. Clin. Microbiol. 35:2487-2491.

[Logo omitted]
South Dakota
State University

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31 December 2002

Mr. Glen Rogan
Monsanto Regulatory Affairs (BB3N)
700 Chesterfield Parkway
Chesterfield, MO 63017

Dear Mr. Rogan:

Following are responses to three questions sent to us by Dr. Sharie Fitzpatrick at Forage Genetics International.

Q1. To the best of your knowledge, is feral alfalfa a weed species that is controlled on roadsides or other unmanaged areas in your state?

A1. No, feral alfalfa is not a weed species in roadsides. In fact, alfalfa is planted with other species along most roads (including interstate highways) in South Dakota.

Q2. If alfalfa is a species that is controlled, what are the herbicides or cultural management practices that are currently used for its control?

A2. Again, alfalfa is a desired component of most roadside mixtures. Therefore, it will not typically be controlled with herbicides or with other practices.

Q3. If you suspected that the Roundup Ready trait was possibly present in feral alfalfa populations, what herbicides or management practices would you use to control feral alfalfa?

A3. Most managers would probably use a herbicide such as 2,4-D, Dicamba, or Tordon to attempt to eliminate Roundup resistant feral alfalfa. One or more tillage operations may also be used if a new seeding is to be done.

It is important to note that many miles of roadsides are harvested each year. Producers who successfully bid a segment of road or highway are allowed to cut in the roadside after a specific date, usually after 14 July. This date is set to allow for optimum wildlife nesting habitat, specifically pheasants. Essentially all of the feral alfalfa will have flowered by this date allowing significant outcrossing to occur. There are quite a number of organic producers in South Dakota. The presence of Roundup resistant alfalfa close to their operations (either on roadsides or in adjacent fields) may threaten their organic status.

Please contact us if you need further clarification about feral alfalfa in South Dakota.

Sincerely,

s/ Vance Owens
Dr. Vance Owens
Forage Research Agronmist

s/ Sharon Clay
Dr. Sharon Clay
Weed Scientist

cc: Dr. Sharie Fitzpatrick

JA-110

Levis W. Handley

07/15/2004 03:19 PM

To: Virgil D. Meier/MO/APHIA/USDA@USDA, Bruce MacBryde/MD/APHIS/USDA@USDA

cc:

Subject: Alfalfa Seed Production in the Western United States

An interesting article about alfalfa seed production and seeds for sprouts. It is hard to find any information about where seeds for sprouts come from. Looks like it can be from almost anywhere. The organic sprouts folks may have a lot to say about this. It may be hard to guarantee that seeds or sprouts are GE free.

http://alfalfa.ucdavis.edu/seed/Seed Production/Western_alf_seed_production.htm

[Logo omitted]

"Steve Tiwald" <stiwald@hotmail.com>

To: regulations@aphis.usda.gov
cc:

Subject: Docket No. 04-085-1

01/20/2005 05:24 PM ID: 04-085-1 (13)

TO:
Regulatory Analysis and Development, PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE:
Round-up Ready Alfalfa Docket No. 04-085-1

I am a vegetable and alfalfa farmer who strongly opposes the introduction of glyphosate resistant alfalfa. This is of great concern to me. My 60-acre farm is located in northern Illinois and I grow lots of alfalfa for cover crop and to feed horses. My vegetables and alfalfa are certified organic and Round-up ready alfalfa is a real threat to my crops and my livelihood.

Yes, it is a plant pest risk. Alfalfa is cross-pollinated by bees, and this creates an opportunity for genetically modified (GM) alfalfa to cross-pollinate with organic alfalfa, thereby causing GM contamination of the seed produced by the organic alfalfa. Along with the threat of cross-pollination creating GM contaminated progeny, seeds from GM fields can also be transported to a field by wind/animals/dirty equipment, and volunteer GM plants will result. Organic farmers with contracts to

provide non-GM alfalfa seed will lose their contracts if even the slightest amount of GM contamination is detected. We have already seen what happens with the "seed invasion" by GM canola and soybeans which have blown into the fields and germinated, or have cross-pollinated with their crops and produced GM contaminated seed. Roundup Ready alfalfa also poses this cross-pollination threat to crops. I understand that Forage Genetics' response to these concerns is that they have seen no cross-contamination between crops at least 2,000 feet apart during their two-year field trial. However, other studies showed that escaped mutated alfalfa plants can be produced by plants a great distance away. This alternative data suggests that it is not possible to contain the transgenic material within the seed/hay fields under current agricultural production techniques, as long distance escaped plants were discovered during the study which could produce GM contaminated populations. (See Amand P., Skinner, D., and Peaden, R. 1995 June. Risk of Alfalfa Transgene Dissemination and Scale Dependent effects. Symposium on Environmental-Releases of Biotechnology Products: Risk Assessment Methods and Research Progress. Pensacola, Florida. Available from: http://www.nbiap.vt.edu/brarg/brasym95/amand95.htm

Another difficulty in determining "safe" distances from GM crops is that field trials are done on a small-scale, which skews the results, and does not provide an accurate representation of gene flow from large-scale farming operations (see Moyes, C. and Dale, P. 1999 May. Organic Farming and Gene Transfer from Genetically Modified Crops. MAFF Research Project

OF0157. John Innes Centre, UK. Available from: http://www.gmissues.org/organic%20report.htm). The percentages may be very small for the chance of GM contamination to a crop, but if even a few GM contaminated seeds develop, they will be directly in the field, and the chance of cross-pollination with the organic alfalfa is then great.

Lastly, you wanted comments about the potential environmental impact of genetically modified alfalfa. I know there will be increases in pesticide usage because that is what I have seen with my neighbors who use Roundup-Ready soybeans. More pesticide usage will increase pesticide residues on neighboring vegetable crops, such as mine, because the drift cannot be contained.

Please do not allow the introduction of genetically modified alfalfa.

Steve Tiwald
10S404 Knoch Knolls Road
Naperville IL 60565

[Logo omitted]

Sequoia77@aol.com
01/24/2005 12:19 PM

To: regulations@aphis.usda.gov
cc:
Subject: Docket No. 04-085-1
ID: 04-085-1 (239)

January XX, 2005

Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road – Unit 118
Riverdale, MD 20737
regulations@aphis.usda.gov
http://www.aphis.usda.gov/ppd/rad/cominst.html

Re: Comments – Monsanto Roundup Ready Alfalfa
Docket #04-085-1

To Whom It May Concern:

I am a small organic farmer opposed to the deregulation of Monsanto's herbicide tolerant alfalfa variety currently being considered by the USDA in the docket referenced above. I have a wide variety of concerns that, as yet, have not been fully evaluated by the USDA and other regulatory agencies.

Like its RR predecessors, Monsanto's RoundUp Ready GE alfalfa poses serious risks, but it also poses some new and unique risks that must be fully addressed, including a full environmental impact statement (EIS), before commercial approval.

RoundUp Ready alfalfa would be the first genetically engineered perennial agronomic crop with the RR trait, and the dynamics of a RR perennial are somewhat different from those of annual crops like

corn and soy, presenting somewhat different risks. For annual crops, the time span for using glyphosate (RoundUp) is one growing season; for perennial crops, multiple applications can be made for several years (alfalfa is usually grown for 3-5 years)(Doll, Jerry D. The Future of RoundUp Ready Alfalfa. 2003. Proc. Wisconsin Fertilizer, AgLime, and Pest Management Conf. Vol. 42), resulting in an overall increase in herbicide usage. It is estimated that in California alone, this could result in as much as 200,000 pounds more herbicides a year(National Center for Food and Agriculture Policy. Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture – An Analysis of 40 Case Studies – "Herbicide Tolerant Alfalfa". June 2002. Gianessi, Leonard P.; Silvers, Cressida S.; Sankula, Sujatha; Carpenter, Janet E).

The RoundUp Ready cropping strategy encourages excessive herbicide application over a longer period of time during the growing season, which can leadto leaching into the soil and groundwater and the absence of cover crops (treated as weeds with RoundUp), which would deprive the soil of their soil-building and nutrient stabilizing benefits (Pridham, Jaqueline. The Impact of RoundupReady Alfalfa on Organic Systems. 2003). Alfalfa is cross-pollinated by bees, creating the very real possibility of RR alfalfa cross pollinating with neighboring conventional and organic alfalfa crops. For organic producers this could cost them their certification, as alfalfa is relied on not only as animal feed, which must be GE-free in order to be used in an organic system, but also as a nitrogen-fixer in their soil. Neither of these options are viable if GE alfalfa is

present in an organic producers fields. Alfalfa plays an integral role in replenishing nitrogen in the soil as green manure and maintaining soil nutrient levels (Pridham, Jaqueline. The Impact of RoundupReady Alfalfa on Organic Systems. 2003). For both organic and conventional growers this contamination possibility poses incredible risks to their livelihoods as well as our environment.

The RoundUP Ready System in Alfalfa Production

Already, RR soy and corn are widespread in US acreage. Commercializing RR alfalfa would hand over three of the top four US field crops to Monsanto's RR system. This possibility brings up many issues.

Increased Herbicide Use

Already, there have been five-fold increases in glyphosate use in the US because of the adoption of the RR system. Alfalfa will be no exception. Given this rise in use, there are potentially significant impacts on biodiversity and human health due to increased levels of toxic chemicals on our food. Glyphosate is generally believed to be immobile in soil as it readily binds to soil particles; however, a recent study found that glyphosate can be readily released from soil particles, and therefore may leach into water. Though glyphosate itself is believed to have a relatively low acute toxicity to mammals, preparations of glyphosate often include a surfactant that increases toxicity to fish and other aquatic species. There are some indications that chronic exposure to glyphosate can be harmful if administered at high doses over long periods of time (MacRae, Rod; Penfound, Holly; Margulis, Charles. Against the Grain: The Threat of Genetically Engineered Wheat. Greenpeace. November 2002.).

RoundUp can be toxic to fish depending on several factors including hardness of water, the age of the fish and water temperature. In some situations, concentrations as low as 10 parts per million can kill fish.

Changes to Weed Populations and Impacts on Biodiversity

As RoundUP becomes the main herbicide used in RR crop systems, weed populations tend to shift. As RoundUp use is increased and substituted for other products, the result is a shift in what weed species survive. These changes could ripple through the ecosystem as food sources for birds and insects change or disappear through this weed control program. In addition, spray drift to borders and neighboring native vegetation can cause damage to wild plants and flowers. This can also lead to harmful effects on birds, insects and other animals that depend on this vegetation for food or shelter. There may also be impacts on soil biota due to over-reliance on one herbicide. Researchers in Arkansas found that glyphosate has a negative effect on a nitrogen fixing bacteria that lives in association with soybeans. Another recent study showed a higher incidence of a fungal disease, Fusarium, on soybeans treated with Glyphosate. These suggest that increased glyphosate use may disrupt soil organism population dynamics. This can have a large effect on the ecosystem because changing soil dynamics usually trigger changes in crop management, often leading to more fertilizers, changes in crop rotation and more or different pesticide applications, these in turn have larger impacts on the soil and ecosystem (MacRae, Rod ; Penfound, Holly;

Margulis, Charles. Against the Grain: The Threat of Genetically Engineered Wheat. Greenpeace. November 2002.).

RoundUp Resistant Weeds

With the increase in adoption of the RR system comes the increase of RR-resistant weeds. After just 6 years of widespread planting, RR crops may have doubled the number of glyphosate-resistant weeds that developed in the previous 25 years (Canon, S. 2001. Weeds Developing Resistance to Widely Used Herbicide, Some Say. The Star (Kansas City), 21 August 2001.). Scientists have already documented glyphosate-resistance in many problem weeds. In 2001, Marestail (Horsegrass) was found to survive even 10 times the recommended application rate of RoundUp. Waterhemp, Ryegrass and Quackgrass have also presented signs of resistance. The number of resistant weeds is expected to increase, and as such will force farmers to use additional, and likely more toxic, herbicides to manage these resistant weeds.

Alfalfa Poses Unique Risks

As alfalfa is used primarily for livestock feed, many questions arise as to how such a change in diet could effect the livestock and the products they produce. Alfalfa is used in feed for dairy cows because it is lower in fiber and higher in protein than any other single forage. Eighteen pounds of alfalfa provides one-third of the fiber, over a third of the crude protein, one-fourth of the energy and half of the calcium required for a high level of milk production (National Center for Food and Agriculture Policy. Plant Biotechnology: Current and Potential Impact for Improving Pest Management in U.S. Agriculture – An Analysis of 40

Case Studies – "Herbicide Tolerant Alfalfa". June 2002. Gianessi, Leonard P.; Silvers, Cressida S.; Sankula, Sujatha; Carpenter, Janet E.). There are currently studies underway examining the risks of transgenes from feed being passed on to gut microflora in livestock – a huge concern in the case of alfalfa. Recent studies have also questioned whether genetically engineered crops have the same chemical composition as their conventional counterparts. The biotech industry has always claimed that the GE varieties are "substantially equivalent" and that nothing but the gene they have introduced has changed. But scientists are beginning to see differences in GE and non-GE crops. A 1999 independent study analyzed the phytoestrogen concentrations in two varieties of genetically modified herbicide tolerant soybeans and their conventional counterparts grown under similar conditions. An overall reduction in phytoestrogen levels of 12-14 percent was observed in the genetically altered soybean strains(Alterations in Clinically Important Phytoestrogens in Genetically Modified, Herbicide-Tolerant Soybeans. Journal of Medicinal Food v.1, n. 4, 1jul99. Marc A. Lappé, Ph.D., Center for Ethics and Toxics, Gualala CA E. Britt Bailey, M.A., Center for Ethics and Toxics, Gualala, CA Chandra Childress, M.S., Children's Hospital Medical Center, Cincinnati, OH Kenneth D.R. Setchell, Ph.D., Children's Hospital Medical Center, Cincinnati, OH). Phytoestrogens, which include lignans and isoflavones are oestrogen-like compounds which occur naturally in many plants and fungi and which are biologically active in humans and animals. Soybeans are rich sources of phytoestogens in the human diet and are currently

believed to reduce the risk of certain cancers, especially those which are hormone dependent such as breast and prostate. Such a change in nutritional value in GE alfalfa could greatly diminish its value as animal feed.

Another significant difference between forage and grain production is that weed control in alfalfa seldom results in higher forage yields as compared to soy, corn or wheat. This is because weeds are usually harvested along with the alfalfa for feed. In fact, overall forage yields may be lower when weeds are controlled and higher when they are not (Doll, Jerry D. The Future of RoundUp Ready Alfalfa. 2003. Proc. Wisconsin Fertilizer, AgLime, and Pest Management Conf. Vol. 42).

In addition, While only 5% of US grown alfalfa is exported, 75% of those exports go to Japan. If RR alfalfa is allowed on the market those exports could be lost. The largest buyer in Japan has already stated they would not buy any US wheat if GE wheat was commercialized due to concerns of contamination and lack of segregation in our current agricultural system. Alfalfa could likely face the same rejection.

I believe Monsanto's RoundUp Ready alfalfa poses serious ecological, agronomic and health risks while offering little benefit to farmers and no benefit to consumers. Commercializing RR alfalfa will benefit only Monsanto's corporate profits at the expense of consumers, farmers and the environment. As such, I believe a full EIS is needed to fully evaluate the possible impacts before commercial approval is considered.

Thank you for taking my comments into consideration.

Sincerely,

Seth Rosmarin
PO Box 943

[Logo omitted]

"DAVIDFGOULD" <davidfgould@msn.com>

To: <regulations@aphis.usda.gov>
cc: "Karri Stroh" <kstroh@ics-intl.com>
Subject: Docket No. 04-085-1

01/24/2005 06:36 PM ID: 04-085-1 (312)

Date: 24 January, 2005

To:
Animal Plant Health Inspection Service
United States Department of Agriculture
http://www.aphis.usda.gov/ppd/rad/cominst.html

Comments Pursuant to:
Docket No. 04-085-1
Monsanto Co. and Forage Genetics International; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate

Submitted by:
International Certification Services, Inc.
5449 45th St. SE
Medina, North Dakota 58467
Tel: 701-486-3578 Fax: 701-486-3580
e-mail: info@ics-intl.com

Introduction:
International Certification Services, Inc. (ICS) is an organic products certification agency based in North Dakota, USA, doing business worldwide. The program

currently does business under the name International Certification Services, as well as Farm Verified Organic (FVO) and has done so since 1980. ICS is accredited by The United States department of Agriculture under the National Organic Program (NOP), International Organic Accreditation Services, Inc. (IOAS) to the program requirements of the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Program. ICS also holds accreditation by USDA for compliance under ISO Guide 65 requirements.

Herewith ICS addresses its comments to Docket No. 04-085-1, Monsanto Co. and Forage Genetics International; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate.

Comments:

ICS believes very strongly that the proposed genetically engineered alfalfa definitely will become a plant pest, and as such must be regulated carefully to protect producers, consumers, livestock, and land from being adversely affected by any introduction of it to the environment and food chain.

Alfalfa is primarily an insect-pollinated crop. Outcrossing of pollen and therefore genetic material from one plant to another is thus inevitable and uncontrollable. The transference of the genetic trait to the receiving plant and its progeny will therefore spread beyond the borders of the land parcels where the genetically engineered alfalfa is planted to other

sites where there was no intention to plant or receive such an altered crop.

This poses serious threats to a variety of producers whose customers state that they do not want to purchase and/or consume genetically engineered products. Income losses for organic producers could be significant, as production standards worldwide for certified organic goods prohibit the inclusion of products using products of genetic engineering. Even in cases where such use is unintentional on the part of the organic producer, certain markets effectively bar the inclusion of contaminated products into the organic market stream. Additionally, conventional producers who cater to markets that specify a requirement or preference for non-genetically altered goods. The European, Japanese, and other markets already have demonstrated such preferences and concomitant export sales losses on a wide scale to American producers.

Furthermore, the losses to producer income will not stop at the level of the crop itself, as the animals that are fed on this genetically engineered forage as well as their products (e.g., dairy or meat products) will meet with the same type of market rejection.

Aside from the market losses, the negative environmental effects of planting such a crop will become obvious in a short time, as already been shown with other similarly engineered crops, such as canola and soybeans. The evolution of weeds and other unwanted species that are resistant to the herbicide glyphosate will develop as outcrossing and transfer of the altered traits to other alfalfa crops or relatives of the *Medic* or related families occurs. This will result in farmers having to use more toxic herbicides to control

weeds that cannot be eliminated with glyphosate. Lands infested with herbicide resistant weeds lose value, making resale or possibilities for use decline.

As seed stocks become contaminated with the engineered alfalfa, it will become impossible to ensure that seed will be free of the altered seed, thereby causing potentially serious problems in the future for all alfalfa crops.

There should be real concern on APHIS' and USDA's part about the unknown effects of the genetically engineered alfalfa, and this should not to be taken lightly. The brief history of other genetically engineered crops has already clearly shown that serious environmental and nutritional problems are associated with genetically engineered species, many of which effects were completely unforeseen or unintended. The litany of such unintentional deleterious effects will not be elucidated here in the interests of saving time and space, but we would be pleased to offer such data at APHIS' request. Our agency and many others have already expounded upon such cases in other comments to APHIS, USDA, and FDA pursuant to other Federal Register notices about genetically engineered products, and are a matter of public record.

That such effects will occur, even if we do not know exactly what they will be, is understandable. APHIS and USDA need to recognize that all organisms exist with a biological mandate toward homeostasis; when the organism's internal balance is disturbed, compensatory reaction by the organism results to restore that balance. When bioengineering is the source of the disruption, the organisms is likely to

resort, if necessary, to respond with an equally foreign homeostatic response. The results must be studied cautiously and thoroughly if the public is to be protected. What the nutritional profile of the engineered alfalfa will be and what its effects on livestock and subsequently human health will be, as well as what kinds of effects this genetically engineered deep rooting plant will have on soil and plant biology, remains to be seen. The potential results may be negative, far-reaching, and irreversible.

There is no compelling agronomic or nutritional reason to introduce this genetically engineered alfalfa into the environment. There are no clear benefits it will provide, save for the financial profit of the petitioners. Any perceived benefits to producers are far outweighed by the environmental and market risks involved.

III. Conclusion

We appreciate the opportunity to offer our comments and share our concerns. We strongly encourage APHIS and USDA to deny the petitioners' request. We would be pleased to contribute additional data and commentary in support if such action.

End of comments.

Respectfully submitted,

David Gould, on behalf of
International Certification Services, Inc.

[Logo omitted]

"Emily Brown Rosen" <ebrownrosen@earthlink.net>

To: <regulations@aphis.usda.gov>
cc:
Subject: Docket No. 04-085-1
01/24/2005 07:04 PM ID: 04-085-1 (315)

January 24, 2005

Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737

Re: Evaluate Herbicide-Tolerant Alfalfa Fully Prior To Allowing Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to Glyphosate:

Comments to USDA's APHIS on Docket No. 04-085-1

I support the the Organic Trade Association (OTA) position and oppose the nonregulated status for the herbicide-tolerant alfalfa at this time. I am a concerned consumer, and agricultural professional advising certified organic farmers. I am particularly concerned that a full environmental impact statement (EIS) be required prior to commercial approval.

I also request that APHIS consider the following points and recommendations.

1) This alfalfa would be the first genetically engineered perennial crop with the trait for glyphosate tolerance. The dynamics of a perennial are different

from those of annual crops like corn and present different risks. These should be identified and resolved before proceeding.

2) Alfalfa is cross-pollinated by bees, creating the very real possibility of RR alfalfa cross pollinating with neighboring conventional and organic alfalfa crops. For organic producers this could cost them the added value of their crops as organic. Alfalfa is cross-pollinated by bees, which are known to travel up to **two miles** when foraging. This creates the very real possibility of RR alfalfa cross-pollinating with neighboring conventional and organic alfalfa crops. Although the USDA has stated recently that unintentional contamination of organic crops will not affect certification status of organic crops, the organic marketplace strongly resists the introduction of GM products. Evidence of contamination of organic crops, despite the USDA pronouncements, will undermine the organic label in the eyes and pocketbooks of consumers world-wide. The USDA received an unprecedented number of public comments in 1997-1998 regarding the possible allowance of GM products in organic agriculture – over 275,000 members of the public demanded that this be excluded. The USDA's failure to protect the organic label by recognizing the danger of unintended contamination of genetically engineered crops is causing liability for organic farmers and could result in lost of marketplace for US organic crops. (see the Organic Farming Research Foundation, 4th Annual Survey http://www.ofrf.org/publications/survey/GMO.SurveyResults.PDF)

3) Until an environmental impact statement has been completed, I remain concerned about the ecological

effects of a glyphosate-resistant perennial, including possible changes to weed populations, impacts on biodiversity, and the need for a resistance strategy for glyphosate-resistant weeds.

4) Each instance of a gene being introduced into a plant variety, let alone specie, is a separate event, and calls for an early food safety evaluation and the identification of possible safety concerns. The whole organism should be evaluated.

5) There are currently studies underway examining the risks of transgenes from feed being passed on to gut microflora in livestock, a grave concern in the case of alfalfa, which is largely used for livestock feed.

6) Recent studies have also questioned whether genetically engineered crops have the same chemical composition as their conventional counterparts. The biotech industry has always claimed that the GE varieties are "substantially equivalent" and that nothing but the gene they have introduced has changed. But scientists are beginning to see differences in GE and non-GE crops. A 1999 independent study analyzed the phytoestrogen concentrations in two varieties of genetically modified herbicide tolerant soybeans and their conventional counterparts grown under similar conditions. An overall reduction in phytoestrogen levels of 12-14 percent was observed in the genetically altered soybean strains (*Alterations in Clinically Important Phytoestrogens in Genetically Modified, Herbicide-Tolerant Soybeans.* Journal of Medicinal Food v.1, n. 4, 1 July 1999. Marc A. Lappe, Ph.D., Center for Ethics and Toxics, Gualala CA; E. Britt Bailey, M.A., Center for Ethics and Toxics, Gualala, CA; Chandra Childress,

M.S., Children's Hospital Medical Center, Cincinnati, OH; Kenneth D.R. Setchell, Ph.D., Children's Hospital Medical Center, Cincinnati, OH).

7) While only 5% of US grown alfalfa is exported, 75% of those exports go to Japan. If this alfalfa is allowed on the market those exports could be lost. The largest buyer in Japan has already stated they would not buy any US wheat if GE wheat was commercialized due to concerns of contamination and lack of segregation in our current agricultural system. Alfalfa could likely face the same rejection.

In conclusion, I believes this new alfalfa may pose serious ecological, agronomic, and possibly even human health risks. Unless a full environmental impact statement is completed, APHIS will not have performed due diligence in its oversight of this new and problematic plant.

Thank you for your consideration.

Emily Brown Rosen

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[Logo omitted]

Theresa Podoll
<tpnpsas@drtel.net>

To: regulations@aphis.usda.gov
cc:
Subject: Docket No. 04-085-1
ID: 04-085-1 (337)

01/24/2005 09:52 PM

Docket #04-085-1

Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737
E-mail: regulations@aphis.usda.gov

Dear Sir:

I am writing on behalf of the Northern Plains Sustainable Agriculture Society requesting that a full environmental impact study be conducted on genetically engineered (GE) "Roundup Ready" (RR) alfalfa before it is commercially released. Alfalfa is a crucial forage in many livestock production systems, both organic and conventional. Its high protein content and its yields surpass other legume forages. Alfalfa also plays an integral role in providing nitrogen in the soil in organic and conventional cropping systems through use as a green manure or by being cycled through livestock as manure. Many farmers, including organic producers, rely on alfalfa to maintain soil nutrient levels and organic matter. In addition, alfalfa is not just a forage crop. Alfalfa seed is also consumed as a health food in the form of sprouts.

Alfalfa is a perennial crop, which poses a unique environmental risk that has not been assessed. In addition, this perennial plant is cross-pollinated by bees, allowing for cross pollination at a distance. Field scale plots do not provide accurate data on of how far pollen will travel or at what distances cross pollination can occur when RR alfalfa is grown on large-scale farming operations.

Along with the threat of cross-pollination creating progeny containing GE traits, seeds from GE fields can also be transported by wind, animals, and farm equipment, resulting in volunteer GM plants. Unlike corn and soybeans, North Dakota's ditches are full of volunteer alfalfa plants. Even a low level of gene escape to volunteer plants in road ditches and public lands would pose continually increasing levels GE presence of field, crop and seedstock contamination. These factors pose a serious threat to organic farming systems, the exporting of alfalfa forages, and to the alfalfa sprout industry.

Finally, the Roundup Ready system of weed control already shows signs of breaking down through increasing numbers of weeds developing resistance to glyphosate. As super weeds emerge, chemical control will have to shift to more toxic and persistent herbicides, greatly impacting the environment.

These factors necessitate a complete environmental impact study on the potential release of Roundup Ready alfalfa.

Sincerely,

Theresa Podoll,
NPSAS Executive Director

Theresa Podoll
Northern Plains Sustainable Agriculture Society
9824 79 St SE
Fullerton, ND 58441
Phone: 701-883-4304
E-mail: tpnpsas@drtel.net

[Logo omitted]

Kristina Hubbard
<kristina.hubbard@gmail.com>

To: regulations@aphis.usda.gov
cc:
Subject: Docket No. 04-085-1
01/25/2005 12:08 AM ID: 04-085-1 (345)

TO:
Regulatory Analysis and Development, PPD, APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238
RE:
Round-up Ready Alfalfa Docket No. 04-085-1

The environmental impacts of GE alfalfa mirror those of current GE crops on the market. These impacts include an increase in pesticide use, weed resistance to glyphosate, and cross-pollination with conventional varieties of alfalfa. Contrary to the message imparted by chemical and biotechnology corporations, pesticide use has increased since the advent of genetically engineered crops. A recent study looked at USDA statistics for the first nine years GE crops were adopted and found that herbicide use has increased by 138 million pounds (Benbrook 2004). The total amount of herbicides applied to RR corn fields in 1996 was 1.88 pounds, whereas in 2003 it had increased to 2.29 pounds per acre (Benbrook 2004). For annual crops, the time span of using glyphosate is one growing season; for perennial crops, single or multiple applications can be made for several years, usually three to five (Doll 2003). In California alone, it is

estimated that this could result in 200,000 pounds more herbicides a year (Gianessi et al. 2002).

In addition to more chemicals entering the environment, there is solid evidence that problematic weeds are becoming tolerant to glyphosate. Herbicide use results in the evolution of tolerance, the ability to compensate for damage, when individual plants with traits that allow them to survive and reproduce pass on their genes to the next generation (Roy 2004). Survivors increase in number over time, and evolve the genetic composition of the population (Roy 2004). These "superweeds" create even bigger challenges, often leaving farmers no other choice but to resort to more toxic pesticides that these herbicide-tolerant crops were supposed to wean out.1 Midwestern farmers have found extensive resistance to glyphosate products in Marestail, a highly problematic weed. Glyphosate-resistant marestail also infested a documented 20,000 acres in the Delaware-Maryland-eastern Virginia peninsula and in southern New Jersey (Pollack 2003). In the South, farmers have experienced resistance in lambsquarter, and in California, the same has been true for ryegrass. Populations of ryegrass in Australia showed resistance to Roundup after as few as seven applications (Muntz 2002). In the Southeastern United States, the tall morning glory is a noxious crop weed whose negative effects on agriculture have been largely mitigated by the use of glyphosate (Baucom and Mauricio 2004).

No single herbicide is designed to control all weeds. Once an herbicide is used, weeds that are tolerant to that herbicide are favored, and over time there is a shift in the weed species present. UC Davis specialist, Mick Canevari, has seen a weed shift in his

experimental plots where Roundup Ready alfalfa has been grown for three years. "When we started this study, there were four or five stinging nettle plants on [one] end of the field. . .Now you can see nettle all along the field. We're seeing more and more nettle each year" (Ascribe Higher Education News Service 2004).

Furthermore, many county road crews use Roundup to control feral alfalfa along roadsides, raising legitimate concerns that cross-pollination will quicken these non-commodity plants' resistance to glyphosate (Cline 2004). Currently, the U.S. Department of Agriculture does not have rules in place that require farmers who plant RR seeds to create refuge or buffer areas to avoid cross-pollination with neighbors' crops or surrounding weeds. The best weed control in alfalfa has always been a thick healthy crop and cultural practices that maximize alfalfa vigor, such as proper variety selection, seedbed preparation, and planting date (Tickes and Orloff). All of these factors give alfalfa the competitive edge it needs to minimize weed infestations. Alternatives already exist for controlling weeds without injuring newly seeded alfalfa. Farmers have successfully used standard postemergence herbicides for controlling major alfalfa weeds, specifically sethoxydim and clethodim (Doll 2003).

U.S. Department of Agriculture statistics shows that the use of glyphosate has dramatically increased in U.S. soybean crops, while there is a concomitant decrease in the use of other herbicides (NASS 2003). Because RR technology affords farmers the opportunity for more frequent applications of glyphosate herbicides, no longer needing to spray on a spot basis, foreseeable harms from more frequent exposures, and potentially at higher levels, need to be

considered. Some of the symptoms recorded by the EPA the following the evaluation of 94 people exposed occupationally to glyphosate include broncial constriction, blurred vision, conjunctivitis, contact dermatitis, headache, nausea, abdominal pain, vertigo, and nervous system disorders (EPA 1980). A later EPA report ranked glyphosate third in the number of illnesses and injuries reported in California from exposure to pesticides from 1980 to 1984, the primary incidents related to eye and skin irritation (EPA 1993).

Resorting to highly toxic chemicals for controlling weedy alfalfa relatives would inevitably extirpate beneficial organisms. One study showed a 98% decrease in young honey bees when older honey bees were fed the lowest concentration of 2,4-D (Morton 1972). Another study showed a 22% decrease in bee populations in a field applied with an aerial spray of 2,4-D (Palmer-Jones 1964). Forage Genetics International touts that this technology will reduce chemical use, however, these researchers admit that Roundup is weak on some of the most important alfalfa weeds, including malva, nettle, hairy fleabane and filaree (Ascribe Higher Education News Service 2004).

Currently, alfalfa farmers use Roundup to kill their 3-5 year stands in order to proceed with their crop rotation, usually to corn. Researchers involved in the development of RR alfalfa have stated that farmers who decide to grow this alfalfa variety must plan on using 2,4-D to kill their stands (Cline 2004).

According to the Environmental Protection Agency (EPA), 2,4-D causes neurotoxicity and gastrointestinal tract complications in humans. There is evidence that it may also promote tumor growth and disrupt the

endocrine and reproductive system. The state of Montana is ranked second in the country for the amount of 2,4-D released into the environment (Environmental Defense).

Alfalfa is the most important forage crop grown in the U.S. because of its role as a nitrogen-fixing plant. There is evidence that 2,4-D reduces the nitrogen fixation by rhizobium, the bacteria formed on nitrogen-fixing nodules on legume roots (Arias 1993). Applications of glyphosate to young soybean plants have shown delay in nitrogen fixation and reduction in soybean root growth (King et al. 2001). Should the nitrogen-fixing abilities of alfalfa be reduced, farmers could find themselves depending on higher concentrations of fertilizers. Increased levels of nitrates in soil and water create additional environmental hazards, not to mention are an added input cost to farmers. Nitrates are now the most ubiquitous water pollutants in the Western world, causing ills ranging from stomach cancer to declining bird populations (Huxham 1999).

In addition to weed resistance to herbicides, the impact of GE alfalfa on migratory birds and pollinators are also cause for concern. Alfalfa is an important wildlife habitat. Birds of prey feed in alfalfa fields and leafcutter and honey bees are the primary pollinators of alfalfa plants. Herbicide spraying in alfalfa fields reduce nectar sources for wild bees, and because many bees have a flight period that extends beyond the availability of alfalfa flowers, bee populations have shown massive declines due to the lack of suitable nesting sites and alternative food plants (Benedek 1972).

Because alfalfa is a cross-pollinating crop, the dissemination of transgenic traits from RR fields to organic fields is a very real threat. In less than a decade, Canada has lost approximately $2 million in the organic canola market, as contamination of organic canola fields and seed sources has become widespread and uncontrollable (Smyth et al. 2002). A recent report published by the Union of Concerned Scientists confirms this rampant spread of transgenic material here in the U.S., showing that half of the conventional corn and soybean seed supply and over 80% of the conventional canola seed supply have some trace of transgenic traits, despite not being marketed as GE varieties (Mellon and Rissler 2003).

Montana's organic industry is at particular economic risk. The state is ranked third in the U.S. for total organic cropland and second in total certified acres. It is ranked second for cultivation of organic alfalfa. Cross-contamination is a huge threat to organic producers, as current laws do not protect farmers from the adventitious presence of patented genetic traits transferred from a neighbor's field. Organic alfalfa farmers risk losing a 40-50% premium on their product, not to mention decertification, if the rate of contamination in Canadian RR canola is repeated by RR alfalfa production here in the U.S. (Guerena and Sullivan 2003).

Researchers at Kansas State University studied alfalfa pollen drift and found that complete containment of transgenes within alfalfa seed or hay production fields would be highly unlikely using current production practices (St. Amend et al. 2000). Of nearly 3,000 progeny analyzed, 3.06% carried the molecular marker that researchers were tracing to determine the

distance pollen traveled from one alfalfa plant to another (St. Amend et al. 2000). Alfalfa is unique in that it is the first perennial plant genetically engineered to tolerate an herbicide. Because this forage crop is grown in increments of 3-5 years, the rate at which plants with adventitious amounts of transgenic traits spread within and between fields is much greater than annual crops. The researchers confirmed alfalfa pollen drift for distances up to 270 meters (approximately 800 feet). Forage Genetics International, the producer of RR alfalfa, confirmed traces of pollen drift at an even greater distance: 1500 feet (Fitzpatrick et al. 2000). Lacking from both of these risk assessment studies is an investigation of scale dependencies of the data.

Another concern is yield. With the commercialization of RR soy and corn came promises of significant yield increases. This was not the case. At least one study shows a yield drag of 5-10% in RR soybeans when compared to conventional varieties (Benbrook 1999). A significant difference between forage and grain production systems is that weed control in alfalfa seldom results in higher forage yields because weeds are harvested with the alfalfa; in fact, yields may be lower in the seeding year when weeds are controlled than when they are not (Hall 1995). A study conducted at Texas Tech University showed no difference in yield when comparing field trials of glyphosate-tolerant alfalfa to conventional alfalfa (Braden et al. 2002).

The economic feasibility of growing RR alfalfa has not yet been studied because Monsanto has not announced the pricing formula for the alfalfa seed. The "technology fee" that Monsanto tacks on to its RR seed

products has steadily increased since coming to the market in 1996. This year, the technology fee for RR soybeans increased 41%, almost $14 per bag, as compared to $6.50 just last year (Skorr 2004). Roundup Ready alfalfa poses unique risks to U.S. farmers and the environment. For all of the reasons outlined above, I ask that you not approve this novel seed variety.

Sincerely,

Kristina J. Hubbard

Missoula, MT

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February 16, 2005

Docket No. 04-085-1
Regulatory Analysis and Development
PPD, APHIS Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: No. 04-085-1

This message addresses a concern pertaining to Docket No. 04-085-1 regarding the determination of non-regulated status for alfalfa designated as Events J101 and J163. These Events have been genetically engineered for the purpose of bringing tolerance to the herbicide glyphosate to the alfalfa crop. My request is that further studies be conducted prior to the deregulation of these Events, as not enough is known about the pollen control aspect of this technology.

To date much progress has been made with genetically engineered corn and soybean crops. Both producers and industry have benefited from these advancements. We must be thorough in the review of bringing the new technology to additional crops and we must be cognizant of the major differences within those crops so we do not jeopardize the accomplishments already made in the existing major crops of corn and soybeans. There are significant differences in the alfalfa crop when compared to these crops.

Pollinators such as honey bees, leafcutter bees, alkaline bees and other wild pollinators transfer pollen from alfalfa plants. Bees are not required to transfer pollen in corn or soybeans. There is an additional problem

with seed production area concentration and the use of pollinators. The specific problem is that the alfalfa seed crop in the United States is produced in very concentrated areas where alfalfas containing these Events and normal alfalfas are grown with no discernable areas of separation. The areas include the Pacific Northwest, California and the Great Plains. As a scientist that has worked with alfalfa seed my entire career, I am not convinced that we have enough answers to the question of pollen control at this time to warrant deregulating these Events.

I bring to your attention the fact that the providers of this technology recently agreed to change the level of isolation needed to produce alfalfa seed containing these events in California. The change was major in scope, as the original isolation proposal of 900 feet was changed to an isolation distance of 3 miles. This change was made after a scientist from the University of California at Davis reported pollen contamination at a distance of 2 ½ miles. This change was made as a result of feedback received from seed growers as well as the public and private sectors of the alfalfa seed industry in the California market. I feel it is the USDA and APHIS who should establish the isolation distance standards for all alfalfa seed production areas including California, the Pacific Northwest, and the Great Plains.

There is now a system comprised of dual standards. The California seed market standard of 3 miles is different than the 900 feet standard in place for the Pacific Northwest and the Great Plains areas. However, the scientists and the alfalfa seed growers in these other areas share the same pollen contamination concern as the California growers. While the primary

source of pollinators in California is the honey bee and the primary source of pollinators in the Pacific Northwest is the leafcutter bee, the fact remains that there are many honey bees present in the Pacific Northwest, as well as wild pollinators and alkaline bees. Alkaline bees are known to fly great distances in search of pollen, presenting a very unique element that should be thoroughly reviewed. Honey bees also fly great distances and are used throughout the Pacific Northwest as pollinators for other crops, although they are not the primary source of pollinator for the alfalfa seed crop. Despite this scenario, no public research has been brought forth to sample production and monitor the level of pollen escape from fields in close proximity to the genetically engineered fields in the Pacific Northwest or Great Plains production areas.

The growing number of issues that can arise from an incompletely studied approach towards adventitious presence and pollen contamination are many.

First, it is important to point out that the alfalfa seed industry and alfalfa seed producers are just being initiated to the issue of genetically modified crops.

Second, the size of the alfalfa seed is quite small when compared to seed corn or soybeans (225,000 seeds per pound when compared to 1,800 per pound for seed corn and 3,000 per pound for soybeans). As a result the prospect of contamination during handling is very real and the issue of volunteer alfalfa containing these events is an item that has not been sufficiently addressed. While there are no problems with volunteer corn or soybeans sprouting along the roadways in the Corn Belt, there is a very strong likelihood of volunteer alfalfa sprouting along the

roadways in the alfalfa seed production areas. This problem becomes exacerbated when considering the perennial nature of the crop. Therefore, a study should be done to characterize the effect and impact of GMO-alfalfa escape, whether by volunteer (by time element) or unintentional release to roadsides and ditches (by spatial element). This indirect contamination can impact the seed export economies of the states where alfalfa seed is grown – particularly California.

Third, due to the high geographic concentration of the alfalfa seed production areas, a genuine concern exists among seed growers and the seed industry as to who will be obligated to purchase the seed crop from a non-genetically modified alfalfa seed field that has been contaminated by a genetically modified alfalfa due to pollen transfer. Seed companies will not want to purchase the crop as they cannot sell it if it exceeds adventitious presence levels. The seed company will not however want to lose control of the genetics and the intellectual property of the non-modified variety. As a result, the grower also has no alternative use and the seed company will not want to pay for a crop that cannot be sold. Thus far, the providers of this technology have not stated whose responsibility it will be to pay the grower if the seed crop is contaminated by pollinators carrying GMO pollen.

Fourth, no systematic sampling and testing of non-GMO alfalfa seed fields in areas adjacent to the GMO alfalfa seed fields has been proposed, much less a funding mechanism to support such sampling and testing, or the provision for an economically acceptable model of compensation for the grower or the owner of

the intellectual property lost when contamination exceeds adventitious presence levels.

US producers have benefited from wonderful breakthroughs thanks to genetic engineering of some of our major crops. However, based on the above I feel we are not yet prepared to bring this technology to the alfalfa crop. Therefore, I respectfully request that approval to deregulate these Events be withheld until further study pertaining to pollen flow and isolation provide the concrete results which will allow us to go forward with the confidence that we can responsibly handle the unique issues that a genetically engineered alfalfa crop raise.

Respectfully submitted,

Dr. William H. Davis
1109 Yonkers
Plainview, TX
s/ William H. Davis

[Logo omitted]

"Kathy Price" <lkjprice@widaho.net >

To: regulations@aphis.usda.gov

cc:

Subject: Docket No. 04-085-1

02/17/2005 09:47 PM ID: 04-085-1 (522)

February 17, 2005

Subject: Docket No. 04-085-1

My grandfather started our family-owned alfalfa seed farm in 1939 and we have been raising alfalfa seed as it's main source of income for 65 years and processing seed for 34 years. We are now into the 4th generation of our family growing and processing alfalfa seed.

I have a few concerns with the release of GMO Alfalfa. My concerns are not based on it's health issues or the science behind the technology; my concern is with the cross-pollination of GMO Alfalfa with non-GMO alfalfas and the loss of markets for the conventionally bred varieties that may contain traces of GMO.

The non-GMO alfalfa seed markets that I am fearful of loosing to other alfalfa seed producing countries are:

USDA Exports of Alfalfa (Lucerne) Seed, Certified-2003:

Country	Pounds	Value
Argentina	2,843,054	2,984,794
Canada	3,081,409	2,867,626
Mexico	2,689,347	3,390,765
Saudi Arabia	9,995,218	13,465,602
Europe	1,429,333	1,170,979

Any one of these markets may be threatened without some type of system in place to guarantee non-GMO Alfalfa Seed production standards are met. Market loss may happen if any of the above countries would not approve GMO Alfalfa before the release in the United States.

Another market concern is the organic alfalfa seed market and their assurance of non-GMO presence in their seed and alfalfa hay. This is an expanding market we have ventured into.

My solution to this issue would be to establish production zones for non-GMO and GMO Alfalfa Seed and possibly for alfalfa hay. One way to achieve this would be to utilize the use of state administered control zones. This has been used for GMO Grass Seed production in central Oregon.

I would like to request the USDA Animal and Plant Health Inspection Service to seriously consider the idea of a control zone for non-GMO Alfalfa production to be in place before any GMO Alfalfa is released to the general public.

Please allow our alfalfa seed farm to be able to operate in a manner that provides non-GMO Alfalfa Seed in the market place. Thank you for considering my concerns.

Sincerely,
Larry D. Price
Price Seed Farms LLC
1681 Hwy 201,
Adrian, Oregon 97901

JA-151

Monsanto Company and Forage Genetics International Petition 04-110-01p for Determination of Nonregulated Status for Roundup Ready® Alfalfa Events J101 and J163

USDA/APHIS Environmental Assessment and Finding of No Significant Impact

May 2005

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment in response to a petition (APHIS Number 04-110-01p) received from Monsanto Company and Forage Genetics International seeking a determination of nonregulated status for their genetically engineered alfalfa designated as events J101 (OECD unique identifier MON-00101-8) and J163 (OECD unique identifier MON-00163-7) under APHIS regulations at 7 CFR Part 340. The plants have been engineered with a gene that confers tolerance to the herbicide glyphosate. Based on the analysis documented in its environmental assessment, APHIS has reached a finding of no significant impact (FONSI) on the environment from the unconfined cultivation and agricultural use of events J101 and J163 and their progeny.

John T. Turner
/s/ John T. Turner for Cindy Smith
Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: 6/14/05

JA-152

USDA/APHIS Environmental Assessment

Monsanto Company and Forage Genetics International Petition 04-110-01p for Determination of Non-regulated Status for Roundup Ready® Alfalfa Events J101 and J163

October 2004

The Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, has prepared an environmental assessment in response to a petition (APHIS Number 04-110-01p) received from Monsanto Company and Forage Genetics International seeking a determination of non-regulated status for their genetically engineered alfalfa designated as events J101 (OECD unique identifier MON-00101-8) and J163 (OECD unique identifier MON-00163-7) under APHIS regulations at 7 CFR Part 340. The plants have been engineered with a gene that confers tolerance to the herbicide glyphosate.

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services

Date:
June 14, 2005

Attachment
Finding of No Significant Impact
Response to Comments
APHIS No. 04-110-01p

APHIS received 663 comments by the close of the comment period. Comments came from alfalfa growers and seed producers, organic growers, animal producers, growers associations, consumer groups, agriculture support industries, academic professionals and individuals. Five hundred twenty respondents did not support granting non-regulated status to the petition. One hundred twenty-seven support the petition. The majority of alfalfa growers and seed producers support granting non-regulated status. They state that their markets demand a weed free product and glyphosate tolerant alfalfa offers a tool to achieve these results. Many of those that do not support the petition are concerned that certain domestic and foreign markets may be closed to growers who cannot guarantee a non-genetically engineered product. The majority of academic professionals, agricultural support industries, and grower's associations also supported the petition. Organic growers opposed the petition because of concerns that pollination of their crops by the glyphosate tolerant variety will result in the inadvertent generation of unwanted GE products, resulting in market loss. The comments raised several issues and each is addressed below.

Several comments suggested that glyphosate tolerant alfalfa may impact exports of conventional or organic alfalfa seed and hay if they contain traces of glyphosate tolerant alfalfa. Several of these comments also suggest that animal products from animals fed

glyphosate tolerant alfalfa could have less market appeal. Many of the comments focused on potential impacts to export markets, especially Japan, which imports approximately $500 million of US alfalfa annually. Of the 5% of alfalfa hay exported, 75% of these exports go to Japan. Japan has not yet agreed to import glyphosate tolerant alfalfa.

USDA believes that all methods of agricultural production (conventional, organic, or the use of genetically engineered varieties) can provide benefits to the environment, consumers, and farm income. The role of Biotechnology Regulatory Services within APHIS is to provide regulatory oversight that allows for the safe development and use of genetically engineered organisms. Once a new biotech variety has been granted non-regulated status by APHIS, any decisions to produce or market that product are made by the technology providers and producers and are driven by market demand. USDA encourages the developers of new biotech varieties to seek regulatory approvals for these new products in our major export markets at the same time non-regulated status is sought within the US, to help prevent loss of markets that could result from unapproved genetically engineered products entering the export channels. The USDA Grain Inspectors, Packers, and Stockyard Administration (GIPSA) announced in August 2002 that they will be developing voluntary testing and process verification programs to facilitate the marketing of agricultural products such as non-genetically engineered varieties.

Japan is a major market for U.S. exports of alfalfa hay. The petitioner has applied for approval for glyphosate tolerant alfalfa for use in food and feed in Japan.

Additionally, Japan allows up to 1% of a genetically engineered product that has not been approved in Japan in feed if that product has completed a safety assessment by a foreign government with an assessment system equivalent to the Japanese (Ministry of Agriculture, Forestry, and Fisheries Announcement 1781, 2002.) This tolerance provides an allowance for those hay producers that export their hay to Japan and are concerned about trace levels of biotech alfalfa in non-biotech shipments. By employing reasonable quality control, it is highly unlikely that the level of glyphosate tolerant alfalfa will exceed 1% in conventional alfalfa hay. This can be accomplished by appropriate oversight of planting, harvesting and transportation equipment, as well as managing storage facilities and checking seed sources.

APHIS received several comments from growers of organic and conventional alfalfa who express concern that gene flow may occur between glyphosate tolerant alfalfa and conventional alfalfa. Alfalfa is an insect pollinated crop that is mainly pollinated by bees. Commenters related that bees can travel relatively long distances and so the potential exists to move pollen from the glyphosate tolerant crop to hay fields, seed fields, and wild or feral populations of alfalfa. The commenters suggest that there will eventually be wild or feral glyphosate tolerant alfalfa plants and that these plants may serve as an additional source for glyphosate tolerant alfalfa gene flow into conventional and organic alfalfa fields.

APHIS acknowledged in the Environmental Assessment that alfalfa is insect pollinated. Insect pollination for alfalfa has been documented up to 2 miles from the pollen source. However isolation

distances are not required for genetically engineered products that have been approved by EPA, FDA, and USDA for general release into the environment because the safety of these products has been thoroughly evaluated by the involved agencies. Nevertheless, the National Organic Program, which is administered by USDA's Agricultural Marketing Service, requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances, such as modified genes, from adjoining land that is not under organic management. However, the determination of the size of the buffer zones is left up to the organic producer and the certifying agent on a case-by-case basis. Furthermore, organic production operations must develop and maintain an organic production system plan that outlines the steps it will take to avoid cross pollination from neighboring operations.

Some comments expressed concern that the glyphosate tolerant trait, if established in feral alfalfa, may move from feral alfalfa to organic seed fields. Other comments provided by alfalfa and weed scientists indicated that most of the existing wild or feral populations appear to be plants from older alfalfa varieties. They speculate that these populations started during earlier times when hay was grown to a much more mature development stage resulting in the production of viable seeds. During its harvest and transportation, this hay along with the viable seed was scattered and the seeds germinated and established to form these feral populations. For the present alfalfa hay production programs, it is highly recommended that the alfalfa be harvested by 10% bloom to maximize

nutritional quality. If the alfalfa is harvested at the recommended growth stage, no mature seeds should have developed. If no mature seeds are produced, viable seeds will not be scattered during the hay harvest or transportation. If no viable seeds are scattered, the establishment of new populations of feral glyphosate tolerant-alfalfa plants should be greatly minimized.

Comments from alfalfa and weed scientists also discussed why feral alfalfa should be a very minor issue. If feral plants are pollinated from a nearby glyphosate tolerant alfalfa seed or hay field and viable seed are produced on the feral plants, seeds that drop from the plant would not germinate and establish because of autotoxicity. If the seeds drop away from the mother plants or other feral plants, alfalfa needs a fairly precise environment for germination and establishment – firm seed bed (alfalfa seed does not germinate well on a hard soil surface), neutral pH, no competition from other plants, adequate water, appropriate N-fixing bacteria, etc. All of these appropriate conditions are very difficult to have in place at the same time in unmanaged locations. APHIS agrees with this comment that establishment of feral glyphosate tolerant alfalfa should be a minor issue and subsequent pollination from those plants would also be a minor issue. The alfalfa seed producer would have the greatest influence on the number of feral plants, glyphosate tolerant or not, near the seed field. The removal of feral plants is strongly recommended near any seed field in which maintenance of varietal purity is a high priority, such as for foundation and certified seed fields of glyphosate tolerant-alfalfa, conventional alfalfa, or organic alfalfa. Good management, combined

with the low likelihood of glyphosate tolerant feral alfalfa, can make this scenario very unlikely to occur.

Some commenters expressed concern that feral alfalfa is considered an invasive plant in some environments according to the USDA/National Resource Conversation Service and the addition of glyphosate tolerance will cause control problems of glyphosate tolerant alfalfa plants in the future.

USDA/National Resource Conservation Service Plants Database Fact Sheet for alfalfa (http://plants.usda.gov/cgi_bin/topics.cgi?earl=characteristics.html) stated that alfalfa may become invasive in some regions or habitats. However, the author of the original document from which the "invasive" terminology was derived commented: "Under NO circumstances was my intention to directly state or imply that alfalfa was invasive, or a noxious and potentially invasive plant species. Instead, I simply intended through its inclusion in the guide to note that alfalfa can, and sometimes does colonize disturbed areas and seemingly occupies a role in those areas as a ruderal." (Brett Serviss, Docket No. 04-085-1 #480).

The information provided in the petition showed that the glyphosate tolerant alfalfa has no more invasive characteristics than conventional alfalfa. Several alfalfa or weed scientists commented that alfalfa is not invasive or a serious weed that would cause major problems. APHIS concurs with this assessment.

A few comments were expressed by those opposed to granting non-regulated status to glyphosate tolerant alfalfa because total forage yields, especially during the seed establishment year, would be lower when weeds are controlled in the glyphosate tolerant alfalfa with

glyphosate as compared with the conventional alfalfa where weeds are not controlled (Doll, 2003).

Total vegetative yield is not the major consideration for alfalfa, but rather forage quality, drying time, palatability, etc. of the harvested product (Doll, 2003). It is acknowledged that vegetative yield from weeds may increase overall yield. However, weeds may be detrimental for livestock feed and decrease premiums for pure alfalfa hay because weeds in general do not have the high nutritional characteristics of alfalfa, some weeds have awns, spines and thorns that that can get stuck in the animals mouth and throat causing injury, some weeds such as wild garlic and onions result in off flavors in meat and milk, and some weeds are poisonous causing death or injury. In fact, the paper that was cited (Doll, 2003) to indicate that controlling weeds may lower overall yield also noted that glyphosate tolerant alfalfa has many advantages over conventional alfalfa. The author of this paper also commented in favor of deregulating glyphosate tolerant alfalfa (Doll, 04-085-01, Comment # 505).

Several comments suggested that glyphosate tolerant alfalfa may have an adverse effect on insectivores protected by the International Migratory Bird Treaty and state protected species that feed on species associated with alfalfa.

With specific reference to the Migratory Bird Treaty Act (MBTA)(16 U.S.C. §701 et seq.), which the commenter cites, APHIS has found no direct effects of glyphosate tolerant alfalfa or the management practices associated with glyphosate tolerant alfalfa on any non-target organism, including migratory birds. The commenter suggests that potential indirect effects on the broad environment of migratory birds by

agricultural practices would violate the MBTA. The Migratory Bird Treaty Act is violated by taking, killing or possessing a listed bird (16 U.S.C. §703). According to 50 C.F.R. 10.12, a "take" within the meaning of the MBTA includes, "to pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to pursue, hunt, shoot, wound, kill, trap, capture, or collect." Since glyphosate and glyphosate tolerant alfalfa management practices associated with those crops do not constitute a taking, this act would not apply.

With respect to indirect effects on agricultural ecosystems that may result from glyphosate use irrespective of the MBTA, APHIS believes these are negligible. Agricultural areas by their very nature are subject to alternating disturbance schedules from season to season. Alfalfa, like many crops, is grown in rotation with other agricultural products. What may be a suitable site for a migratory bird one year may be inhospitable in the next. There exists no requirement that growers manage their land to maximize or optimize habitat for migratory birds.

The FDA has primary regulatory authority over food and feed safety. FDA has completed their consultation and had no further questions about the food or feed safety of alfalfa derived from events J101 or J163 submitted by Monsanto and Forage Genetics, Inc. http://www.cfsan.fda.gov/~rdb/bnf1084.html

Information can be found for alfalfa along with other deregulated crops at http://www.cfsan.fda.gov/~lrd/biocon.html. Sections V.C, V.D, and V.F of the petition address the characterization and biochemical properties of the CP4 EPSPS protein produced by Events J101 and J163. Each of these sections showed that the CP4 EPSPS protein is similar

to the EPSPS protein of control plants and has the same properties as the *E. coli* produced CP4 EPSPS protein. Section VI.H addresses the crop compositional assessment. This section showed the composition of the forage derived from the plants with Events J101 and J163 in comparison with control plants and reference varieties to being very similar with any differences noted to be unlikely to have any biological significance. In addition, two feeding studies on broilers using canola meal and corn both of which were tested for their nutritional value using materials with and without CP4 EPSPS showed similar performance between the transgenic product and nontransgenic control (Taylor et al., 2003 and Taylor et al., 2004). The above information provides evidence that the glyphosate tolerant alfalfa should perform similar to nontransgenic alfalfa for birds and other animals. Similar information can be found in the 1999 OECD Consensus Document.

In relation to wildlife habitat, the National Wild Turkey Federation that supports scientific wildlife management on public, private and corporate lands commented that alfalfa is an excellent wildlife plant material providing food and shelter and voiced their support for the petition since they felt the glyphosate tolerant alfalfa should benefit wild turkeys, other birds, such as migrating and over-wintering water birds and waterfowl, and other wildlife species that utilize alfalfa fields.

Several groups and individuals involved with organic food production expressed concerns that liability or economic issues may be created by finding small amounts of glyphosate tolerant alfalfa seed in seed for sprouting used in human food, by finding transgenic

genes or proteins in organic animal products (such as milk, meat and honey) or finding hay with some small level of glyphosate tolerant alfalfa. The economic loss may result from not meeting contract specifications, failing to meet certification standards, or losing market share for not meeting consumer expectations and preferences. These concerns about economic issues also raised concerns on liability issues such as who would be liable for any unexpected losses caused by identifying low levels of glyphosate tolerant alfalfa in products expected to be free of glyphosate tolerant alfalfa. It is up to the individual organic seed or hay grower to institute those procedures that will assure meeting any specified claims or contract specifications that are beyond the normally accepted specifications or standards for the crop, in this case alfalfa seed and hay. One commenter pointed out that the official position of the International Federation of Organic Agriculture Movements (IFOAM) is that *"Organic certification shall not imply it is a "GE-free" certification. Rather it shall be presented as guaranteeing "production without GE/GMOs". As there is no guarantee that organic products are 100% free from any GMO pollution, organic products shall not be marketed as "GE-free", unless there are specific safeguards and certification procedures for that specific product. Organic producers and associations shall actively inform the consumers of this fact to ensure fair marketing claims and to avoid future debates about consumer deception."* This statement is part of the official position Adopted by the IFOAM World Board, Canada May 2002.

A group of commenters oppose the petition because they believe that each release of another glyphosate

tolerant crop, in this case glyphosate tolerant alfalfa, leads to increased use of glyphosate and other herbicides resulting in increased environmental harm to groundwater, watersheds, drinking water, fisheries, irrigation, soils, and wildlife refuges. They also suggest that increased glyphosate use leads to more glyphosate resistant weeds, which require the use of more toxic herbicides. They also suggest that glyphosate tolerance in perennial crops encourages excessive herbicide application over longer periods during the growing season and over multiple years in the same area. Some believe that stewardship of glyphosate use should be considered to conserve this environmentally friendly herbicide. Many of these comments also suggest that the release of glyphosate tolerant alfalfa will result in the use of more toxic herbicides to control glyphosate tolerant alfalfa, because in many cases fields of alfalfa are now removed using glyphosate, so with the use of glyphosate tolerant alfalfa, herbicides with higher toxicity ratings, such as 2,4-D and dicamba, would be used to remove the glyphosate tolerant alfalfa; and glyphosate is often used to control weeds, including feral alfalfa plants, in nonagricultural environments such as roadsides, so herbicides with higher toxicity ratings would be required to control feral glyphosate tolerant alfalfa plants.

Many of the comments about herbicides incorrectly assume that herbicides are not used on alfalfa seed fields or hay fields presently. In reality, several different herbicides may be used multiple times throughout the multiyear lifespan of the typical alfalfa seed or hay field and may be applied multiple times within the same year depending on the weeds that need to be controlled. Most, if not all, of these

herbicides, have a less desirable environmental profile (toxicity, decay rate, movement into groundwater, etc.) than glyphosate, most have restrictions that limit their flexibility of use, most do not control as many of the weeds, and most cause some damage to the alfalfa lowering its yield compared to glyphosate.

APHIS disagrees with the comment that glyphosate tolerance in perennial crops encourages excessive use of glyphosate because it implies that glyphosate would be used incorrectly, used more often than necessary, or used at higher than recommended rates. Applying glyphosate or any pesticide contrary to the label is illegal. Using it more often than necessary or using it at higher than recommended rates are characteristics of uninformed users that care little about the environment or about economics. Based on their comments, alfalfa seed and hay growers are informed users and they care about the environment. They also want to grow and market their products by the most economical means. Extra applications of glyphosate would take additional time and effort. It would require more glyphosate, result in greater equipment use, and may result in greater damage to alfalfa stands. All of these factors would result in greater expense to the producer. Applying glyphosate at higher than recommended rates would also result in greater expense to the producer. APHIS received comments from 34 alfalfa and weed scientists from 21 different states supporting the petition. Most of these scientists have many years (often more than 15 years) of experience working with alfalfa and/or herbicides. They are very familiar with the requirements of growing quality alfalfa while balancing the use of weed

control measures to protect the environment, animal safety and the economic returns of the farmers.

Some commenters are concerned that glyphosate use on glyphosate tolerant alfalfa may result in additional glyphosate resistant weeds. APHIS agrees that this may occur. Weed species have developed resistance to every widely used herbicide. The scientists and growers in the agricultural community are very aware of this potential. A vast body of scientific literature has developed to address this issue. Alternative herbicides and strategies are available that may minimize the problem. Based on the comments, the alfalfa growers and weed scientists understand that good stewardship may be the only defense against this potential problem.

APHIS concurs that if a herbicide is used to remove glyphosate tolerant alfalfa from fields, a herbicide or combination of herbicides other than glyphosate will be used. APHIS realizes that the herbicides used may have an environmental profile that is less favorable than glyphosate. The choice that is made is based on the herbicide(s) registered for such use by EPA, and the grower's needs and preferences.

APHIS also acknowledges that if herbicides are used to remove feral glyphosate tolerant alfalfa plants along roadsides, or in other managed areas, that herbicides other than glyphosate would be used. Based on the comments received from alfalfa and weed scientists, other herbicides are registered and available for such use. In fact, based on the comments from most of these scientists, the need to control these feral plants is very small and glyphosate would not be the herbicide of choice for this control because glyphosate would destroy the companion grasses as well resulting in possible environmental damage.

Some comments suggested that increased use of glyphosate may result in shifts in weed species which in turn can ripple through the ecosystem as food sources for birds and insects change or disappear. In addition, they suggest that spray drift to field borders and nearby native vegetation causes damage to wild plants and flowers. These changes in plant populations can lead to harmful effects on birds, insects and other animals that depend on this vegetation for food and shelter.

With any wide use of a major herbicide, weed shifts are expected since plants may have more or less tolerance to any specific herbicide. This is no different for glyphosate. Maximizing yields of the highest quality crop is one of the most important goals of agriculture. Weeds are a major cause of yield and quality reduction. Therefore, it is not surprising that "diversity" of different plant species tends to be very low in agricultural fields, even in organic production. Maximizing yield in agricultural fields may lessen the need to place more area into agricultural production. APHIS believes that indirect effects on agricultural ecosystems that may result from glyphosate use are negligible. Agricultural areas by their very nature are subject to alternating disturbance schedules from season to season. Alfalfa, like many crops, is grown in rotation with other agricultural products. What may be a suitable site for a bird or insect in one year may be inhospitable in the next. There exists no requirement that growers manage their land to maximize or optimize habitat for birds or insects.

A few comments suggested that the increase in the number of glyphosate tolerant crops leads to over-reliance on one herbicide (glyphosate) with impacts on

soil biota. Two examples suggested in the comments were negative effects on nitrogen fixing bacteria living in association with glyphosate tolerant soybeans (commenters were referring to King, et al., 2001), and higher incidence of fungal disease (Fusarium) on glyphosate tolerant soybeans.

Nitrogen fixing bacteria in soybeans (*Bradyrhizobium japonicum*) are different from the nitrogen fixing bacteria in alfalfa (*Sinorhizobium meliloti*). *S. meliloti* can metabolize glyphosate (Liu et al., 1991). Additionally, while the results of King et al. (2001) demonstrated a negative impact on *B. japonicum*, further investigation into the impact of using glyphosate on glyphosate tolerant-soybeans concluded that there is no significant reduction in yield. (Zablotowicz and Reddy, 2004).

Njiti et al. (2003) concluded that the development of Sudden Death Syndrome (SDS) was influenced by the genotype of the cultivar and not by the presence of the gene for glyphosate tolerance. They showed that there was no higher incidence of Fusarium on glyphosate tolerant soybeans; there was no greater root colonization by the soil-borne fungus *Fusarium solani* in the glyphosate tolerant variety and no more of the expected SDS leaf symptoms following the application of glyphosate. The petition for nonregulated status for glyphosate tolerant alfalfa also indicated that there were no significant differences between the glyphosate tolerant alfalfa and the conventional alfalfa with respect to disease susceptibility and no differences were noted for root nodulation between glyphosate tolerant alfalfa and conventional alfalfa.

A few comments noted that the petition reported an apparent increase in hard seed (seed dormancy) that

may increase weediness of glyphosate tolerant alfalfa and feral glyphosate tolerant alfalfa plants. As noted in the petition, hard seed levels vary considerably in alfalfa and it appears to vary considerably with the environment. APHIS was quite aware of the significantly higher level of hard seed in the glyphosate tolerant alfalfa compared with the conventional variety in the first year that the data were collected. The data provided in the petition in Table VI-6 was the most conclusive information to indicate that glyphosate tolerance does not have an effect on hard seed level. Six scientists from four different states each with more than 20 years experience working with alfalfa and/or seed physiology commented that there was no evidence linking the increased levels of hard seed with glyphosate tolerance. They also generally noted that hard seed in the case of alfalfa was not linked to dormancy since their observations and studies in the past showed that hard seed almost always germinated within a few weeks of seeding and the seedlings that developed were generally too weak and noncompetitive to survive. From the data submitted in the petition and from the comments from these scientists, APHIS concludes that glyphosate tolerance does not cause increased seed dormancy, which may lead to increased weediness.

Some commenters expressed concern that the glyphosate tolerant alfalfa varieties will dominate the market to such an extent that conventional varieties will no longer be available and organic farmers will have no options to buy conventional varieties. This same trend toward popularity of genetically engineered varieties will further decrease the availability of non-genetically engineered varieties

since forage breeders of conventional varieties will have to go to added expense and effort to assure that no transgenes are in the new variety. The commenters suggest that this same trend in variety development will further decrease diversity with a negative impact on the environment. The varieties of alfalfa that are commercially available are driven by market forces. APHIS does not regulate the available varieties of any crop unless it is a plant pest. To do so would extend well beyond the authority of APHIS.

The concern that conventional varieties will no longer be available after the deregulation of glyphosate tolerant alfalfa assumes that this product will be so commercially successful that all future variety improvement programs would concentrate solely on genetically engineered varieties, and that the demand for new improved conventional varieties from farmers is so small that there is very little economic justification for conventional alfalfa variety improvement programs.

There are many conventional alfalfa varieties available now and much of the alfalfa presently grown east of the Mississippi River is grown in combination with forage grasses to be used for grazing or for hay. A glyphosate tolerant alfalfa variety would presumably be more expensive to purchase. To grow it with mixed forage grasses does not appear practical since its major advantage would be the elimination of all other plant species. Therefore the demand for glyphosate tolerant alfalfa would appear to be less east of the Mississippi River than west of the Mississippi River. This may result in demand for conventional varieties.

Some alfalfa seed farmers expressed concerns of seed crop contamination and felt that their respective states should be given authority to establish and monitor production zones to minimize chances for cross contamination and aid in detecting contamination when it occurs.

If APHIS grants non-regulated status to a transgenic event, APHIS does not have any further regulatory authority over this particular transgenic event. Individual states, on the other hand, often have authority to impose some type of regulation over various aspects of the agriculture enterprises within their state, such as establishing some type of production zone, to facilitate production or marketing of specific crops. APHIS would have no regulatory authority over the state to require or to forbid such a production zone.

Some comments expressed concerns of the possibility of transgenes passing from the glyphosate tolerant alfalfa to the gut micro-flora in livestock since alfalfa can be a major portion of a livestock diet.

Transgenic DNA is no different from other DNA consumed as part of the normal diet. Genetically engineered organisms have been used in drug production and microbial fermentation (cheese and yogurt) since the late 1970's. More than 500 million cumulative acres of engineered food and feed crops have been grown and consumed world wide in the past seven years (International Service for the Acquisition of Agri-biotech Applications at: http://www.isaaa.org/kc/CBTNews/press_release/briefs30/es_b30.pdf.) The FDA has not reported any significant concerns with bioengineered food and feed currently on the market. Based on lack of toxicity, the EPA has exempted from

a pesticide tolerance DNA that are parts of plant-incorporated protectants FR 66 37817-37820).

There have been several studies in humans and animals following the fate of DNA once consumed (Beever and Kemp, 2000; Mercer *et al* 1999, 2001; Duggan *et al*, 2000; Chambers *et al.*, 2002; Netherwood *et al.* 2002; Einspanier *et al.*, 2001; Duggan *et al.*, 2003). The majority of DNA consumed is degraded in the gastro-intestinal tract although this is not 100% efficient. There is evidence that both transgenic and plant DNA can move from the gastro-intestinal tract lumen to other areas of the body and that this is a normal occurrence, but no risk has been identified.

Transfer and subsequent expression of DNA from the plant to bacteria is unlikely to occur due to impediments. First, transgene DNA promoters and coding sequences are optimized for plant expression not prokaryotic bacterial expression and the bacteria must be competent to accept DNA. Gebhard and Smalla (1998) and Schluter *et al.* (1995) have studied transgene DNA movement to bacteria, and although possible, DNA transfer would occur at extremely low rates (approximately 1 in 10^{14}). However, many genomes (or part thereof) have been sequenced from bacteria that are closely associated with plants including *Agrobacterium* and rhizobia (Kaneko *et al.*, 2000; Galibert *et al.*, 2001, Wood *et al.* 2001, Kanekko *et al.* 2002). There is no evidence that these organisms contain genes derived from plants. Syvanen (1994), Kumar and Rzhetsky (1996), Koonin *et al.* (2001), and Brown (2003) reviews of the literature using sequencing data reveals that horizontal gene transfer from plants to bacteria occurs occasionally on an evolutionary time scale of millions of years. One of the

factors limiting the frequency of horizontal gene transfer appears to be the need for homologous recombination and there are few homologous sequences between plants and bacteria. As noted in the petition, the gene for glyphosate tolerance was isolated from a soil bacterium, *Agrobacterium*.

One commenter made a reference to a no harm decision from the Fish & Wildlife Service (FWS) and indicated that the analysis is incomplete in that the Environmental Assessment fails to identify what if any species or issues it requested the FWS to address. APHIS and the Fish and Wildlife Service have a long standing agreement about these issues developed from a meeting in July 1999. The agencies agreed to use a decision tree approved by FWS to determine whether consultation with FWS would be required for a transgenic crop variety. APHIS continues to use this decision tree and policy for all petition requests. APHIS considered all threatened and endangered species, but none were identified for consultation with FWS.

Several commenters indicated that commercializing glyphosate tolerant alfalfa will benefit only Monsanto's corporate profits at the expense of consumers, farmers and the environment.

APHIS disagrees with this statement. Approximately 70 comments were received from hay growers in 20 different states (15 of which are west of the Mississippi River) as well as many of the alfalfa and weed scientists that indicated they were looking forward to using the glyphosate tolerant alfalfa to help lower costs, gain increased yields of weed free hay especially in the seeding year, use less water, gain timing flexibility in herbicide application, and decrease usage

of other herbicides that are inconsistent or less effective in controlling weeds, that may injure the alfalfa crop, and that are less environmentally friendly. Of the growers that indicated the number of acres of alfalfa hay on their farms, the acreage ranged from a low of 50 acres to a high of 3000 acres. This large range implies that the size of farm is independent of the expected usefulness of this new technology. In addition, many alfalfa seed growers (10 growers from 6 states) felt that glyphosate tolerant alfalfa would help them be more efficient in controlling weeds at less cost resulting in more profit and at the same time helping to protect the environment by not having to use herbicides that may not be as environmentally friendly as glyphosate.

Another group of comments suggested that the use of glyphosate tolerant alfalfa may benefit some areas because hay is commonly contaminated with invasive weeds, some of which are noxious weeds. One hay grower commented that some of their customers are public entities and private individuals who require Certified Weed Free Forage for use in Yellowstone National Park and the surrounding National Forests in the area to avoid bringing in noxious and prohibited weeds. It is obvious from this comment that if glyphosate tolerant alfalfa makes it easier and more practical to have weed free hay, glyphosate tolerant alfalfa would help to maintain the nation's natural areas and therefore could be an environmental benefit.

Several commenters expressed concerns that glyphosate tolerant alfalfa may have adverse impacts on human or animal health. Some of these comments were concerned that the chemical composition of glyphosate tolerant alfalfa may not be the same as its

conventional counterpart. The commenters were concerned that there would be downstream adverse effects in the human food supply or that since alfalfa is used primarily for animal feed, there may be impacts of glyphosate tolerant alfalfa on livestock The FDA has primary regulatory authority over food and feed safety. FDA has completed their consultation and had no further questions about the food or feed safety of alfalfa derived from events J101 or J163 submitted by Monsanto and Forage Genetics, Inc. http://www.cfsan.fda.gov/~rdb/bnf1084.html Information can be found for alfalfa along with other deregulated crops at http://www.cfsan.fda.gov/~lrd/biocon.html. Some commenters suggested that the continued introduction of glyphosate tolerant crops, in this case glyphosate tolerant alfalfa, would lead to more glyphosate use. This would result in more human exposure to glyphosate. Reports of various symptoms have been attributed to glyphosate exposure (EPA 19080, EPA 1993). The EPA has regulatory authority over pesticide use. EPA has determined the tolerance for glyphosate residue on the alfalfa forage http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-24488-filed and on the alfalfa seed http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocketaccess.gpo.gov/2005/05-2983.htm

One commenter suggested that genetic modification could alter the nutritional value of the crop. The commenter refers to the alleged changes in phytoestrogen levels in glyphosate tolerant soybeans. However further investigations have shown that levels of soyasaponin and isoflavone are similar between genetically modified and non-genetically modified soybean lines (Goda et al., 2002) and application of

glyphosate had little or no effect on estrogenic isoflavones in glyphosate tolerant soybeans (Duke et al., 2002).

Some comments suggested that this petition to deregulate glyphosate tolerant alfalfa warranted an Environmental Impact Statement under NEPA, since this is the first perennial crop to request deregulation, and since APHIS has decided to conduct an EIS on glyphosate tolerant creeping bentgrass (another perennial plant).

APHIS disagrees with these comments. APHIS has thoroughly examined the potential environmental impacts related to granting nonregulated status to glyphosate tolerant alfalfa while preparing an environmental assessment. APHIS has reached a finding of no significant impact after carefully considering the potential impacts of glyphosate tolerant alfalfa. Therefore an EIS is not needed. Some comments erroneously state that this is the first perennial crop to be granted nonregulated status. This however is not the case. The first perennial crop to be deregulated by APHIS was a virus resistant papaya (APHIS No. 96-051-01p, http://www.aphis.usda.gov/brs/aphisdocs2/96_05101p_com.pdf)

APHIS decided to conduct an EIS on glyphosate tolerant creeping bentgrass and not for glyphosate tolerant alfalfa because it was the first petition for a long-lived perennial species, that also spreads easily both vegetatively and via seed and pollen, and that has many wild, and somewhat more weedy relatives with which it can potentially hybridize over long distances, and both creeping bentgrass and its relatives persist in non-agricultural ecologically sensitive environments in which vegetation management options may be more

limited. By comparison (1) creeping bentgrass can persist for many years in non-agricultural environments including riparian areas that are sensitive and critical habitat for wildlife, whereas alfalfa tends to be a short-lived perennial that tends to die out after several years generally because of susceptibility to disease and traffic from animals and farm equipment. Alfalfa is primarily found in well-drained areas in or around agricultural fields or roadsides; (2) creeping bentgrass is wind pollinated and viable pollen can potentially spread many miles depending on wind velocity (Watrud et al., 2004 indicated finding successful hybridization 13 miles from the pollen source), whereas alfalfa is insect pollinated which generally limits potential viable pollen movement to within approximately 2 miles, (3) creeping bentgrass can easily spread vegetatively by means of stolons, whereas alfalfa has great difficulty in vegetative spread since it regenerates itself exclusively from the crown of the plants (it has no rhizomes or stolons), (4) creeping bentgrass, once seeded on the golf course is likely to serve as a potential reservoir for dispersal for 5-10 years before it is potentially replaced with another turf species or variety, whereas alfalfa whether for seed or hay will be part of a normal rotation with other crops, and (5) creeping bentgrass has at least 13 related Agrostis or Polypogon species, (both native and naturalized) within the USA with which it is has been documented to form hybrids (and the transgene could be further passed on to other species through further hybridization and introgression), whereas alfalfa has only one known relative within the *Medicago* genus in the United States, *Medicago lupulina* (black medic), and no successful hybrids have ever been documented

between *Medicago sativa* and *Medicago lupulina* (black medic). APHIS evaluates each petition individually. APHIS considers many aspects of the biology as well as the intended and typical uses of the crop. APHIS diligently complies with NEPA to develop the appropriate documents to aid with the ultimate decision process.

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Appendix A: Biology of alfalfa and the potential for introgression into related species

Appendix B: APHIS authorizations for field tests of Monsanto/Forage Genetics International alfalfa events J101 and J163

Appendix C: Summary table of data submitted with petition 04-110-01p for alfalfa events J101 and J163

Appendix D: Determination of Non-regulated Status for Roundup Ready® Alfalfa Events J101 and J163

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), has prepared an Environmental Assessment (EA) in response to a petition (APHIS Number 04-110-01p) from Monsanto Company (St. Louis, MO) and Forage Genetics International (West Salem, WI) (hereafter FGI) seeking a determination of non-regulated status for their genetically engineered Roundup Ready® alfalfa designated as events J101 (OECD unique

identifier MON-ØØ1Ø1-8) and J163 (OECD unique identifier MON-ØØ163-7). Monsanto Company and FGI seek a determination that events J101 and J163 and their progeny do not present a plant pest risk and, therefore, become no longer regulated articles under regulations at 7 CFR Part 340.

Events J101 and J163 were engineered to be glyphosate tolerant by inserting a gene that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the alfalfa genome. The gene is from the common soil bacterium *Agrobacterium* sp. strain CP4 and was introduced into alfalfa via an *Agrobacterium*- mediated transformation protocol.

This EA specifically addresses the potential for impacts to the human environment through the use in agriculture of events J101 and J163. It does not address the separate issue of the potential use of the herbicide glyphosate in conjunction with these plants. The United States Environmental Protection Agency (EPA) has authority over the use in the environment of all pesticidal substances, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Food and Drug Administration (FDA) has authority over food and feed issues of all plants used as food or feed.

Field trials of J101 and J163 alfalfa have been conducted under APHIS notification procedures (7 CFR 340.3). In accordance with APHIS procedures for implementing the National Environmental Policy Act (NEPA) (7 CFR 372), this EA has been prepared prior to issuing a determination of nonregulated status for J101 and J163 alfalfa in order to specifically address the potential for impact to the human environment through

unconfined cultivation and use of the regulated articles in agriculture.

II. INTRODUCTION

A. Development of Events J101 and J163 Alfalfa

Monsanto and FGI have submitted a "Petition for Determination of Non-regulated Status" to the USDA, APHIS (APHIS number 04-110-01p) for genetically engineered alfalfa that is tolerant to the broad spectrum herbicide glyphosate. Glyphosate tolerant alfalfa would offer farmers a new option for weed control.

The management of weeds in alfalfa fields can be an expensive, labor intensive, and sometimes complicated operation. Often farmers use pre-emergent herbicides that will stop weed seeds from germinating. However, this assumes that weeds will always be a problem in all parts of the field. With J101 and J163 and progeny, farmers will have the option of applying herbicide after weeds have germinated and only in the areas of the field where there are weeds. Glyphosate is one of the most environmentally friendly herbicides commercially available.

These alfalfa plants were genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* sp. strain CP4) that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the alfalfa genome. This gene, along with its regulatory sequences, was introduced into these alfalfa plants via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure, which has been widely used for over a

decade for introducing various genes of interest directly into plant genomes.

APHIS authorized the first field testing of these alfalfa plants starting in 1998 and they have been field tested in the United States under the APHIS authorization numbers noted in Appendix B. Events J101 and J163 alfalfa have been evaluated extensively to confirm that they exhibit the desired agronomic characteristics and do not present a plant pest risk. The field tests have been conducted in agricultural settings under physical and reproductive confinement conditions.

B. APHIS Regulatory Authority

APHIS regulations at 7 CFR Part 340, which were promulgated pursuant to authority granted by the Plant Protection Act (7 U.S.C. 7701-7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. An organism is no longer subject to the regulatory requirements of 7 CFR Part 340 when it is demonstrated not to present a plant pest risk. A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. These alfalfa plants have been considered regulated articles because they contain non-coding DNA regulatory sequences derived from plant pathogens and the vector agent used to deliver the transforming DNA is a plant pathogen.

Section 340.6 of the regulations, entitled "Petition for Determination of Nonregulated Status", provides that

a person may petition the Agency to evaluate submitted data and determine that a particular regulated article does not present a plant pest risk, and therefore should no longer be regulated. If APHIS determines that the regulated article is unlikely to present a greater plant pest risk than the unmodified organism, the Agency can grant the petition in whole or in part. In such a case, APHIS authorizations (i.e., permits or notifications) would no longer be required for field testing, importation, or interstate movement of the non-regulated article or its progeny.

C. U.S. Environmental Protections Agency and Food and Drug Administration Regulatory Authorities

The genetically engineered alfalfa is also subject to regulation by other agencies. The EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 *et seq.*). FIFRA requires that all pesticides, including herbicides, be registered prior to distribution or sale, unless exempt by EPA regulation. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 *et seq.*), pesticides added to (or contained in) raw agricultural commodities generally are considered to be unsafe unless a tolerance or exemption from tolerance has been established. Residue tolerances for pesticides are established by EPA under the FFDCA, and the FDA enforces the tolerances set by the EPA. A final EPA decision is pending.

The FDA policy statement concerning regulation of products derived from new plant varieties, including those genetically engineered, was published in the

Federal Register on May 29, 1992, and appears at 57 FR 22984-23005. Under this policy, FDA uses what is termed a consultation process to ensure that human food and animal feed safety issues or other regulatory issues (e.g., labeling) are resolved prior to commercial distribution of bioengineered food. Monsanto/FGI submitted a food and feed safety and nutritional assessment summary for events J101 and J163 in October 2003. A final FDA decision is pending.

III. PURPOSE and NEED

APHIS has prepared this EA before making a determination on the status of J101 and J163 alfalfa as regulated articles under APHIS regulations. The developer of these alfalfa plants, Monsanto and FGI, submitted a petition to USDA-APHIS requesting that APHIS make a determination that these alfalfa plants shall no longer be considered regulated articles under 7 CFR Part 340.

This EA was prepared in compliance with the National Environmental Policy Act (NEPA) of 1969 as amended, (42 USC 4321 *et seq.*) and the pursuant implementing regulations (40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 372).

IV. ALTERNATIVES

A. No Action: Continuation as a Regulated Article

Under the Federal "no action" alternative, APHIS would not come to a determination that these alfalfa plants are not regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of J101 and J163 lines of glyphosate tolerant alfalfa. APHIS might choose this alternative if

there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of glyphosate tolerant alfalfa.

B. Determination that J101 and J163 Alfalfa Plants are No Longer Regulated Articles, in Whole

Under this alternative, these glyphosate tolerant alfalfa plants would no longer be regulated articles under the regulations at 7 CFR Part 340. Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of glyphosate tolerant alfalfa derived from these events. A basis for this determination would include a "Finding of No Significant Impact" under the National Environmental Policy Act of 1969, as amended (42 USC 4321 *et seq.*; 40 CFR 1500-1508; 7 CFR Part 1b; 7 CFR Part 342).

C. Determination that J101 and J163 Alfalfa Plants are No Longer Regulated Articles, in Part

The regulations at 7 CFR Part 340.6 (d) (3) (I) state that APHIS may "approve the petition in whole or in part." There are two ways in which a petition might be approved in part:

1. Approval of some but not all lines requested in the petition. In some petitions, applicants request deregulation of lines derived from more that one independent transformation event. In these cases, supporting data must be supplied for each line. APHIS could approve certain lines requested in the petition, but not others. This request is for the two events J101 and J163 and their progeny.

2. Approval of the petition with geographic restrictions. APHIS could determine that the regulated article poses no significant risk in certain

geographic areas, but may pose a significant risk in others. In such a case, APHIS might choose to approve the petition with a geographic limitation stipulating that the approved line could only be grown without APHIS authorization in certain geographic areas.

V. POTENTIAL ENVIRONMENTAL IMPACTS

Potential impacts to be addressed in this EA are those that pertain to the use of events J101 and J163 and its progeny in the absence of confinement.

A. Alternative A: No Action

If APHIS takes no action, commercial scale production of events J101 and J163 and their progeny is effectively precluded. These plants could still be grown in field trials for variety development as they have been for the past several years under APHIS authorizations (notifications). APHIS has evaluated field trial data reports submitted on events J101 and J163 and their progeny, and has noted no significant adverse effects on non-target organisms, no increase in fitness or weediness characteristics, and no effect on the health of other plants. The Agency expects that future field tests would perform similarly.

With respect to commercial production, if APHIS were to take no action, alfalfa growers would still have the same options available to them for weed control in their fields as they currently have. Control measures can be complicated by type of weeds (over 90 weeds were reported as being significant in alfalfa), growth stage of specific weeds, growth stage of the alfalfa, carry over effects on the following crops, and field environmental conditions. Statistics presented (Hower et al., 1999,

Gianessi and Marcelli, 2000) on the usage of pesticides on the nation's alfalfa crop (seed and forage) document significant use of 19 herbicides, other than glyphosate, in the U.S. between 1988 and 1997. Planted area of alfalfa during this time period was reported to be 21,000,000 to 23,000,000 acres.

The data on the estimated use of the herbicides in alfalfa in 1997 in the following table are taken from Gianessi and Marcelli (2000) (http://www.ncfap.org/database/default.htm).

Herbicide	Application Rate (Lbs A.I./A)	Total Lbs. A.I. (1000s)
Benefin	1.2-1.35	119
Bromoxynil	0.26-0.45	37
Clethodim	0.1-0.2	4
Diruron	1.2-1.6	271
EPTC	2.6-3.5	695
Glyphosate	0.35-1.45	175
Hexazinone	0.25-1.0	316
Imazethapyr	0.03-0.11	28
Metribuzin	0.25-0.75	319
Norflurazon	1.0-1.5	43
Paraquat	0.25-0.69	355
Pronamide	1.0-1.3	24
Sethoxydim	0.11-0.5	132
Terbacil	0.50-0.64	47
Trifluralin	0.75-2.16	950
2,4-DB	0.3-1.5	389
Total		3,904

A range of application rates were reported, since recommended rates vary based on the type of weeds, environmental conditions and type of herbicide mixture.

In addition to chemical control measures, growers would also likely continue the use of mechanical and cultural practices such as mowing, tillage, burning, flash grazing and companion crops.

B. Alternative B: Approval of the Petition, in Whole

If APHIS were to grant the petition for non-regulated status in whole, alfalfa events J101 and J163 and their progeny would no longer be considered regulated articles. APHIS' assessments of the environmental impacts are discussed in the following sections.

1. Plant pathogenic properties

APHIS considered the potential for the transformation process, the introduced DNA sequences or their expression products to cause or aggravate disease symptoms in alfalfa events J101 and J163 and their progeny or in other plants. We also considered whether data indicate that unanticipated unintended effects would arise from engineering of these plants. APHIS considered information from the scientific literature as well as data provided by the developer when conducting their field trials.

Recipient organism

The plant material used for development of events J101 and J163 was FGI proprietary alfalfa clone R2336 from a high yielding, fall dormant breeding population. The initial plants, selected for tolerance to glyphosate, were designated J101 and J163, and various populations

were developed from these events to provide the data presented in the petition. The breeding history and progeny resulting from events J101 and J163 can be found in Figure VI-8, p. 113 of the petition. Alfalfa is not listed as a Federal noxious weed or on other weed lists such as:

Federal Noxious Weed List (http://www.aphis.usda.gov/ppq/weeds/noxwdsa.html),

Washington State Weed Lists (http://www.nwcb.wa.gov/weedlist/weed_listhome.html),

California Weed Species Lists (http://www.extendinc.com/weedfreefeed/list-b.htm),

Montana County Noxious Weed List (http://www.weedawareness.org/weed%20list.html),

North Dakota Noxious Weeds (http://www.ext.nodak.edu/extpubs/plantsci/weeds/w1103w.htm).

Transformation system

Events J101 and J163 were developed using a disarmed (i.e., pathogenicity genes removed) *Agrobacterium*-mediated transformation system of sterile alfalfa seedling cotyledons. Post-transformation, *Agrobacterium* were eliminated from tissues by a 7-week culture on antibiotic-containing medium. Glyphosate was used to select for transformed tissues containing the *epsps* gene construct. This technique using disarmed *Agrobacterium* followed by selection has a 20-year history of safe use and has been used for transformation of a variety of plant species and tissues (Howard *et al.*, 1990).

DNA sequences inserted into alfalfa events J101 and J163

Data supplied in the petition and reviewed by APHIS (Section V.A., pp. 38-68) support the conclusion that events J101 and J163 contain the following sequences: (1) a 35S promoter from a modified figwort mosaic virus (P-FMV), (2) coding sequence for a chloroplast transit peptide from *Arabidopsis thaliana*, (3) the 5-enolpyruvylshikamate-3-phosphate synthase gene (*epsps*) from *Agrobacterium* sp. strain CP4, and (4) DNA containing polyadenylation sequences from the 3' non- translated region of the *Pisum sativum* (pea) *rbc*S E9 gene. The non-coding 35S promoter is from the plant pathogen figwort mosaic virus. This sequence, however, cannot cause plant disease and serves a purely regulatory function for the *epsps* gene. The *epsps* gene is from the soil-inhabiting bacterial plant pathogen, *Agrobacterium* sp. strain CP4. It encodes the EPSPS protein which functions to impart tolerance to the broad spectrum herbicide glyphosate. It does not cause disease and has a history of safe use in a number of deregulated genetically engineered plants (e.g., corn, cotton and soybean varieties).

Evaluation of intended effects

As expected, as a result of introduction of the *epsps* gene into the alfalfa genome, the resulting plants are tolerant to glyphosate, the active ingredient in the herbicide Roundup®.

Analysis of inheritance: Data were provided and reviewed by APHIS that demonstrate stable integration and inheritance of the *epsps* gene and its associated regulatory sequences over several breeding generations. Statistical analyses show that glyphosate

tolerance is inherited as a dominant trait in a typical Mendelian manner (petition Table V-1, p. 71).

Analysis of gene expression: Data on EPSPS (5-enolpyruvylshikamate-3-phosphate synthase) protein concentrations were collected from field trials conducted at multiple locations. Using standard laboratory ELISA techniques, protein concentrations from alfalfa forage were determined (petition Table V-8, p. 97). EPSPS protein concentrations on a fresh weight basis averaged 257 µg/gram in plants with event J101, 270 µg/gram in plants with event J163, and 252 µg/gram in plants from the population containing both events J101 and J163. EPSPS enzymes are ubiquitous in plants and microorganisms and have not been associated with hazards from consumption or to the environment. Genetically engineered crops that contain this recombinant protein and have been granted non-regulated status include corn, soybean, cotton, rapeseed and sugar beet (http://www.aphis.usda.gov/brs/not_reg.html). In 2004, significant acreages of corn (10.5 million acres or 13% of the total), upland cotton (4.2 million acres or 30% of the total) and soybean (63.6 million acres or 85% of the total) grown in the U.S. were planted with herbicide tolerant varieties (http://usda.mannlib.cornell.edu/). Although the data include all herbicide tolerant varieties, glyphosate tolerant ones (containing EPSPS) predominate. All the genetically engineered glyphosate tolerant varieties have also undergone review by the FDA (http://www.cfsan.fda.gov/~lrd/biocon.html) and are allowed for food and feed use.

Analysis of the intended trait: Numerous field trials were conducted (Appendix B of this EA) to evaluate

events J101 and J163 in different environments. Standard field trials evaluated (1) agronomic performance, (2) disease and pest resistance performance, and (3) seed multiplication. Agronomic practices used to prepare and maintain each field trial were characteristic of each representative region. Where the glyphosate herbicide Roundup® was used in trials, no negative impacts from application of the Roundup® were noted.

Analysis of possible unintended effects: Expression of EPSPS in events J101 and J163 alfalfa is not expected to cause plant disease or influence susceptibility of J101 and J163 or their progeny to diseases or other pests. Data addressing disease susceptibility and overall agronomic performance were collected in order to assess possible effects from introduction of the *epsps* gene and its associated regulatory sequences. The petitioner has described these trials, conducted over several years in a variety of locations, and presented these data in Section VI of the petition (starting on p. 99). Approximately 760 observations were presented in the petition from 18 location-years on susceptibility to disease, insects and weeds. All of the observations noted no differences between the populations with and without events J101 and J163. An additional 152 observations from 15 location-years were presented on abiotic stresses with no differences noted between populations with events J101 and J163 and control populations. Other phenotypic characterizations comparing J101 and J163 populations with conventional and control populations were also completed. Data were provided and assessed by APHIS on numerous characteristics related to the morphology of flowers, pollen and seed, seed germination and dormancy, seed

yield, and various plant growth characteristics such as forage yield, seedling vigor, regrowth after cutting, survival, and fall dormancy. No qualitative or quantitative observations indicated any biologically meaningful differences from control populations or differences outside the range of conventional alfalfa norms. Al-Kaff et al. (1998) have noted gene silencing effects when transgenic plants have been infected by a virus with DNA sequence homology to a portion of the introduced genes. None of the viral diseases of alfalfa is related to figwort mosaic virus (http://image.fs.uidaho.edu/vide/refs.htm and http://www.apsnet.org) (a *caulimovirus*, from which the promoter for the *epsps* gene originates), so silencing of the epsps gene should not occur.

In addition to field studies on agronomic parameters, Monsanto/FGI analyzed alfalfa for compositional changes as part of their submission to FDA in the consultation process. While FDA uses these data as indicators of possible nutritional changes, APHIS views them as general indicators of possible unintended changes. Compositional analyses evaluating carbohydrates, protein, ash, minerals, fiber, lignin, fat, and 18 amino acids (a total of 35 different components) identified three statistically different values compared with the control population for J101, seven statistically different values for J163, and 11 statistically different values for the paired J101 X J163 population. However, all analyses fell within the 99% tolerance interval developed from the conventional varieties grown in the same locations, providing additional evidence that J101, J163 and the paired J101 x J163 populations do not exhibit unexpected or unintended effects.

Potential Impacts on Relative Weediness of Events J101 and J163 Compared to Conventionally Bred Alfalfa

APHIS assessed whether J101 or J163 alfalfa populations are any more likely to become a weed than the non-transgenic control populations or other currently cultivated alfalfa. This assessment considers the basic biology of alfalfa and an evaluation of unique characteristics of J101 and J163 alfalfa populations.

Almost all definitions of weediness stress as core attributes the undesirable nature of weeds from the point of view of humans; from this core, individual definitions differ in approach and emphasis (Baker, 1965; de Wet and Harlan, 1975; Muenscher, 1980; Booth et al., 2003). The parent plant in this petition, *Medicago sativa* L., is not listed as a serious weed in A *Geographical Atlas of World Weeds* (Holms et al., 1991) or as a weed in *World Weeds: Natural Histories and Distribution* (Holms et al., 1997), *Weeds of the North Central States* (http://www.ag.uiuc.edu/~vista/html_pubs/WEEDS/list.html), *Weeds of the Northeast* (Uva et al.,1997), or *Weeds of the West* (Whitson et al., 1992) nor is it listed as a noxious weed species by the U.S. Federal Government (7 CFR Part 360). Occasionally, alfalfa volunteers in fields the year after stand termination. These volunteer plants can be controlled by mechanical means or several other registered herbicides besides glyphosate. Alfalfa possesses few of the characteristics of plants that are notable of successful weeds (Baker, 1965; Keeler, 1989; Booth et al., 2003).

As part of a bilateral agreement between the United States and Canada, USDA/APHIS and the Canadian

Food Inspection Agency (CFIA) have generated documents that outline basic data requirements for developers of genetically engineered plants (http://www.aphis.usda.gov/brs/international coord.html). One of these documents, Appendix II, outlines the environmental characterization data requirements for unconfined releases. As a part of the entire package requesting a determination of non-regulated status, these data are designed to address characteristics that influence both reproductive biology and survival biology of the transgenic plant compared to its non-transgenic counterpart.

In trials conducted in the United States, no differences were observed between J101 or J163 populations and non-transgenic control populations with respect to the plants ability to persist or compete as a weed. APHIS considered data relating to plant vigor, seedling emergence, seed germination, seed dormancy and other characteristics that might relate to increased weediness. No unusual characteristics were noted that would suggest increased weediness of J101 and J163 plants. Additionally, no characteristics relating to disease or insect resistance that might affect weediness were noted. These characteristics were consistent over all field trial locations. J101 and J163 alfalfa plants are still susceptible to the typical insect and disease pests of alfalfa.

Potential Impacts from Outcrossing of Lines J101 and J163 to Wild Relatives

APHIS evaluated the potential for hybridization and gene introgression to occur from J101 and J163 to sexually compatible wild (free-living) relatives, and considered whether such introgression would result in

increased weediness. Alfalfa is sexually compatible with several subspecies within the *M. sativa* complex (Small and Jomphe, 1989). The center of origin for the genus *Medicago* is generally believed to be in the Caucasus, northwestern Iran and northeastern Turkey; the genus is not native in North America (see this EA's Appendix A). An additional 18 *Medicago* species are known to be naturalized (free-living) or possibly so within the United States, of which only *M lupulina* (black medic) is widely naturalized throughout the United States. None of these species are native to the United States, and none are sexually compatible with *M sativa.*

Potential Impact on Threatened or Endangered Species or Non-target Organisms Including Beneficial Organisms

APHIS evaluated the potential for deleterious effects or significant impacts on non-target organisms, including those on the Federal Threatened and Endangered Species (TES) list of the U.S. Fish and Wildlife Service (FWS) (http://endangered.fws.gov/wildlife.html#Species), from cultivation of J101 and J163 alfalfa and its progeny. The gene that codes for the enzyme EPSPS that confers glyphosate tolerance is from the bacterium *Agrobacterium* sp. strain CP4. This gene is similar to the gene that is normally present in alfalfa and is not known to have any toxic property. Field observations of events J101 and J163 revealed no negative effects on non-target organisms. The lack of known toxicity for this enzyme suggests no potential for deleterious effects on beneficial organisms such as bees and earthworms. The high specificity of the enzyme for its substrates makes it unlikely that the introduced enzyme would metabolize endogenous

substrates to produce compounds toxic to beneficial organisms.

A number of researchers have conducted laboratory investigations with different types of arthropods exposed to genetically engineered crops containing the CP4 EPSPS protein (Goldstein, 2003; Boongird et al., 2003; Jamornman et al., 2003; Harvey et al., 2003). Representative pollinators, soil organisms, beneficial arthropods and pest species were exposed to tissues (pollen, seed, and foliage) from genetically engineered crops that contain the CP4 EPSPS protein. These studies, although varying in design, all reported a lack of toxicity observed in various species exposed to these crops (Nahas et al., 2001; Dunfield and Germida, 2003, Siciliano and Germida 1999).

EPSPS has received an exemption from tolerance requirement from the EPA on all raw agricultural commodities (http://www.epa.gov/fedrgstr/EPA-PEST/1996/August/Day-02/pr-840.html). APHIS has not identified any other potential mechanisms for deleterious effects on beneficial organisms.

From the above analysis of both qualitative and quantitative information from the petition and published data, APHIS concludes that the unconfined release of J101 and J163 and their progeny would not harm any non-target or Federally listed (or proposed) threatened or endangered species. Consistent with APHIS' U.S. Fish and Wildlife Service TES assessment requirements, this is a "no harm" decision.

Potential Impacts on Agricultural and Cultivation Practices

Current weed control practices in alfalfa can be somewhat complicated and can vary substantially among spring seedings, fall seedings, and established stands and between hay and seed production. Current practices include mechanical tillage, companion crops, mowing, flash grazing, early harvest, burning, and both pre-and post-planting application of broadleaf and grass herbicides (Hower et al. 1999). Each of these practices has its limitations and can be significantly impacted by growing conditions, soil pH, weed species, target weed size, crop size, cost, etc. Glyphosate, a non-selective herbicide (e.g., Roundup®), would provide post-planting control of most annual grass and broadleaf weeds in glyphosate tolerant alfalfa under a wide range of growing conditions. Glyphosate would control larger broadleaf weeds than currently available herbicides and allow more application flexibility when environmental conditions prevent the timely application required by some currently used herbicides. In addition, glyphosate would provide a different herbicide mode of action in the growers' crop rotation, which is important in preventing the development of herbicide resistant weeds. Glyphosate is applied like any other post-emergent herbicide used in any other crop. Glyphosate tolerant alfalfa may alter current alfalfa cultivation practices by allowing for reduced herbicide use in comparison to current practices in order to achieve the same crop yield.

Alfalfa forms a symbiotic relationship with the bacterium *Sinorhizobium meliloti* (formerly *Rhizobium melilto*), that transforms nitrogen in the atmosphere, which cannot be utilized by the plant, into

a form that is useable by plants. This process of nitrogen fixation reduces the plants dependence on soil nitrogen. *Sinorhizobium meliloti* strains were able to grow on glyphosate as the sole source of phosphorus in the presence of aromatic amino acids (Liu et al., 1991), which indicates that the application of glyphosate on glyphosate tolerant alfalfa should have no effect on the nitrogen fixation process of this symbiotic relationship.

Potential Impacts on Organic Farming

The National Organic Program (NOP) administered by USDA's Agricultural Marketing Service (AMS) requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods. Excluded methods include a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes.

Organic certification involves oversight by an accredited certifying agent of the materials and practices used to produce or handle an organic agricultural product. This oversight includes an annual review of the certified operation's organic system plan and on-site inspections of the certified operation and its records. Although the National Organic Standards prohibit the use of excluded methods, they do not

require testing of inputs or products for the presence of excluded methods.

The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan. Organic certification of a production or handling operation is a process claim, not a product claim.

It is not likely that organic farmers, or other farmers who choose not to plant transgenic varieties or sell transgenic alfalfa, will be significantly impacted by the expected commercial use of this product since: (a) non-transgenic alfalfa will likely still be sold and will be available to those who wish to plant it; (b) farmers purchasing seed will know this product is transgenic because it will be marketed and labeled as glyphosate tolerant.

No transgenic varieties of alfalfa are currently in commercial production. Varieties derived from events J101 and J163 should not present new and different issues with respect to impacts on organic farmers. With the exception of seed production fields, alfalfa does not typically set viable seed in fields used to produce forage. Although these fields may produce flowers that may release pollen, the fields are typically harvested before the seed is set and allowed to mature, because high quality forage is the desired product.

Potential Impact on Sprout Production

Although alfalfa is mainly used for animal feed, humans do consume alfalfa sprouts. APHIS considered the likelihood of events J101 and J163 entering the sprouting industry. The following are the reasons why APHIS considered this use of glyphosate tolerant alfalfa to be a very low probability: (1) Only a small amount (estimated to be about 7%) of the alfalfa seed produced and marketed in the United States is used for sprouting purposes (Bass et al., 1988). (2) Glyphosate tolerant alfalfa seed will be labeled to indicate that it is glyphosate tolerant since this claim is a valuable agronomic characteristic. (3) Glyphosate tolerant alfalfa seed will use many of the conventional practices to maximize seed yield and these recommended practices include the use of pesticides during production (Hower et al., 1999). (4) The seed to be used for planting forage fields will most likely be coated with bacterial inoculant and/or fungicide and colored (petition Addendum 1). (5) Each container of glyphosate tolerant seed to be sold will have a designation (i.e., lot number) that can trace its origin to the field in which it was produced. (6) Applicants intend to produce all glyphosate tolerant alfalfa seed under production contracts that will preclude the legal sale of the seed for food use and forage producers who purchase Roundup Ready (i.e., glyphosate tolerant) alfalfa seed will be required to sign an agreement that expressly prohibits the production of any seed. (7) The sprouting industry endorses the use of certified sprouting seed, the criteria for which include seed production practices such as field history, pesticide use and origin of seed. Each of these criteria by itself would be adequate to disqualify glyphosate tolerant

alfalfa for certified sprouting purposes (DeWaal, 1998; Oregon State University, 2004; International Specialty Supply, 2004).

Potential Damage to Raw or Processed Agricultural Commodities

APHIS review of the information provided by the applicant regarding the components and processing characteristics of these plants revealed no differences in any component that could have a direct or indirect plant pest effect on any raw or processed commodity. APHIS believes that the modifications for herbicide tolerance should not affect this commodity in any significant manner.

Other Environmental Statutes and Considerations

Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects. Each alternative was analyzed in its ability to affect minority and low-income populations. None of the alternatives were found to pose disproportionately high or adverse human health or environmental effects to any specific minority or low-income group.

EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks," acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children. None of the alternatives is expected to have disproportionately high or adverse human health or environmental effects to children.

EO 13112, "Invasive Species", states that Federal agencies take action to prevent the introduction of invasive species and provide for their control and to minimize the economic, ecological, and human health impacts that invasive species cause. The non-engineered plant is grown in the U.S. and based on the data submitted by the applicant and reviewed by APHIS, the engineered plants are not significantly different in any fitness characteristics from their parent that might increase their invasive potential.

Potential Impacts on Biodiversity

After careful evaluation, APHIS believes that events J101 and J163 alfalfa exhibit no traits that would cause increased weediness, that their cultivation should not lead to increased weediness of other cultivated or feral alfalfa or any sexually compatible relatives, and that they are unlikely to harm non-target organisms common to the agricultural ecosystem or Federal threatened or endangered species as recognized by the U.S. Fish and Wildlife Service. Based on this analysis,

APHIS believes that it is unlikely that events J101 and J163 alfalfa or their progeny will pose a significant impact on biodiversity.

Consideration of Potential Environmental Impacts Associated With the Cultivation of Events J101 and J163 outside the United States

APHIS has also considered potential environmental impacts outside the United States and its territories associated with a determination of non-regulated status for J101 and J163 alfalfa. *Medicago sativa* is a prized forage used worldwide; the primary center of the genus is in the Caucasus, northwestern Iran and northeastern Turkey (see the EA's Appendix A). Many of the wild *Medicago* species are annuals, with which the perennial species do not hybridize or hybridize only with great difficulty under natural conditions. None of the *Medicago* species were noted to be serious weeds.

Any international trade in alfalfa subsequent to this determination would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC). The IPPC has set a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention. In addition, issues that may relate to commercialization of particular agricultural commodities produced through biotechnology are being addressed in international forums. APHIS continues to play a role in working toward harmonization of biosafety and biotechnology guidelines and regulations, including within the North American Plant Protection

Organization (NAPPO), which includes Mexico, Canada, and the United States. NAPPO's Biotechnology Panel advises NAPPO on biotechnology issues as they relate to plant protection. APHIS also participates regularly in biotechnology policy discussions at forums sponsored by the European Union, and the Organization for Economic Cooperation and Development (OECD). APHIS periodically holds bilateral or multilateral discussions on biotechnology regulatory issues with other countries (most often Canada and Mexico), and has participated in numerous conferences intended to enhance international cooperation on safety in biotechnology. APHIS has sponsored several workshops on safeguards for planned introductions of transgenic crops, most of which have included consideration of international biosafety issues. All the existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new alfalfa cultivars internationally apply equally to those covered by an APHIS determination of non-regulated status under 7 CFR Part 340.

In 1992, world leaders agreed on a strategy for "sustainable development". One feature of this agreement was the Convention on Biological Diversity (CBD). The U.S. government has not ratified the CBD. One part of the CBD is the Cartegena Protocol on Biosafety, which entered into force on September 11, 2003. The Biosafety Protocol is designed to ensure an adequate level of safety in the transfer, handling and use of "living modified organisms" addressing the potential adverse effects on conservation, sustainable use of biological diversity, taking into account risks to human health. Signatory countries are required to

implement a system to address these issues. The CEQ report's biodiversity considerations for incorporation into environmental impact analysis under the National Environmental Policy Act are similar to those addressed by the Biosafety Protocol.

C. Determination that J101 and J163 Alfalfa Plants are No Longer Regulated Articles, in Part

If APHIS were to grant the petition for non-regulated status in part, alfalfa events J101 and/or J163 and their progeny would no longer be considered regulated articles, with some restriction. If an in-part determination would be a geographic restriction, all of the environmental considerations under Part B would be applicable to such a determination.

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VII. CONSULTATIONS

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Appendix A: Alfalfa biology and the potential for introgression into related species

Medicago sativa L., alfalfa (sometimes called lucerne), is a perennial herbaceous legume (Lesins and Lesins, 1979; Hill, 1987) that is grown worldwide, and is a member of the family Fabaceae (Leguminosae), tribe Trifolieae (Mabberley, 1998; Small and Jomphe, 1989; Quiros and Bauchan, 1988). Alfalfa is insect pollinated, primarily by a few bee species; the flower is specialized and only pollinated once, after which it is tripped and no longer available for insect visitors to pollinate it again (Viands et al., 1988; Hill, 1987). The mature plant has a deep taproot, making it possible to use soil moisture from depths of about 20 feet (6 meters) or more (Teuber and Brick, 1988; Barnes and Sheaffer, 1995). In addition, alfalfa forms a symbiotic relationship with *Sinorhizobium meliloti* (formerly *Rhizobium meliloti*), thereby reducing its dependence on soil nitrogen (Vance et al., 1988; Ferguson et al., 2002). Flowers develop at the shoot apex when the plant transitions from vegetative to reproductive growth, which generally takes place between the 6th and 14th nodes depending on genetics and the environment. The stems are indeterminate, so vegetative and reproductive growth can occur simultaneously (Teuber and Brick, 1988; Viands et al., 1988).

The Old World genus *Medicago* L. (including some *Trigonella* species) consists of about 85 species (Small and Jomphe, 1989; Bena, 2001; Mabberley, 1998), with most being annuals and one quarter or fewer being perennial herbs (and a few shrubs). Domesticated alfalfa (*M. sativa*) originated in Asia Minor, Iran, Transcaucasia and Turkmenistan several millennia ago

(Quiros and Bauchan, 1988; Muller et al., 2003). It can now be found growing wild (free-living) from Spain (Muller et al., 2001) to China and North Africa to Sweden. It has also become acclimatized as a crop in South Africa, Australia, New Zealand, South America and North America. The *M. sativa* complex, which was introduced into North America early by Europeans for forage and includes all the commercial alfalfa varieties, is a group of closely related subspecies, including the cultivated *M. sativa* ssp. *sativa* and *M. sativa* ssp. *falcata* (synonym *M. falcata*) (Small and Jomphe, 1989). Of the 11 other species in *Medicago* section *Medicago* (all of which are perennials), only *M. hybrida* is found free-living in North America (Small and Jomphe, 1989; Quiros and Bauchan, 1988; Michaud et al., 1988; Kartesz, 2004).

In addition to the *M. sativa* complex within which all of the subspecies are sexually compatible to some degree, an additional 17 and possibly 18 *Medicago* species have been recognized as being naturalized (free-living) or possibly so in the United States (USDA-NRCS, 2004; Kartesz, 2004). All of these 18 species are annual species, except for the species *M hybrida* (in *Medicago* section *Medicago*) hybrids of which have only been produced experimentally by embryo culture. No annual species are known to hybridize with *M. sativa* (Quiros and Bauchan, 1988; McCoy and Bingham, 1988; and the petition's Appendix 4).

Medicago lupuhna (black medic) is the species that might be of most concern within this list of 18 species. It is considered a weed in lawns and waste places and in forages since its seeds frequently contaminate forage legume seed crops. Black medic is an annual (possibly sometimes short-lived perennial) self-pollinating

species and is known to occur throughout the United States. Successful hybridizations between *M. sativa* and *M. lupuhna* have been reported (Southworth, 1928; Fryer, 1930; Shrock, 1943). However, because of many subsequent experiments, there is general agreement that these putative "hybrids" were most likely not hybrids but due to self-fertilization (Lesins and Gillies, 1972; Fridriksson and Bolton, 1963; Valizadeh et al., 1996). For more details on this topic, see Section E.1 (p. 284) and Appendix 4 of the petition. Based on all the recent data available on this subject, APHIS' opinion is that hybridization between *Medicago sativa* and *M. lupulina* has an extremely low to non-existent probability of occurring in a non-experimental or even in an experimental setting.

Alfalfa is not considered a serious weed, a noxious weed or an invasive species in the United States, even though feral (free-living) populations are fairly common and volunteers may occur in succeeding crops. Generally feral populations, many of which are along roadsides, are not a problem, and generally no attempts are made to control these populations. In some instances, these feral populations are considered advantageous and are encouraged (petition Appendix 3, p. 375, 12/31/02 Letter from South Dakota State University). More detailed information concerning feral populations of alfalfa and control of feral populations is in the petition's Section E.4 (p. 287), F.3 (p. 293) and Appendix 3 (p. 369). Alfalfa is frequently used in different crop rotations, varying with the region. The use of glyphosate tolerant alfalfa is not expected to change current crop rotation options or patterns. More detailed information on crop rotations is addressed in Section F.1 (p. 291) and Section F.4 (p.

302) of the petition. Less than 100% stand termination can result in volunteer alfalfa plants in the following crop. Therefore good stand termination procedures would still be a good method of eliminating volunteer glyphosate tolerant alfalfa plants. More detailed information on stand termination is addressed in the petition's Section B.6 (p. 259) and specifically for glyphosate tolerant alfalfa in Section E.2 (p. 292). If volunteers of glyphosate tolerant alfalfa are in a crop, management practices and recommendations to control these volunteers can be found in its Sections F.3 (p. 293) and F.5 (p. 303). Based on the available information on this subject, APHIS' opinion is that alfalfa is not an important weed in the United States, but care should be taken with other glyphosate tolerant crops that may be chosen to follow glyphosate tolerant alfalfa.

Possible movement of the transgene via pollen from events J101 and J163 to other members of the *Medicago genus* would be species and geographically specific. Movement of the transgene to plants within the *M sativa* complex can be expected if the plants are located relatively near each other. Based on a search for *Medicago* populations in the United States (http://www.natureserve.org/explorer) 14 matches were found. All of the matches were considered to be non-native species.

APHIS believes that if the glyphosate tolerance trait moves from J101 and J163 to other sexually compatible *Medicago* species in the United States, this will not have a significant impact. Since all *Medicago* species are not native to the Western Hemisphere, there will be no impact on the natural genetic resources of these species from release in the United States. If

glyphosate tolerant individuals did arise through interspecific hybridization, the tolerance would not confer any competitive advantage to these plants unless challenged by glyphosate. This would only occur in managed ecosystems where glyphosate is applied for broad spectrum weed control, or in plant varieties developed to exhibit glyphosate tolerance and in which glyphosate is used to control weeds. As with glyphosate tolerant alfalfa volunteers, these individuals, should they arise, could be controlled using other available chemical and/or mechanical means. Undesired crosses, if they developed, could potentially result in the loss of glyphosate as a tool to control them. However, this can be avoided by the use of sound crop management practices.

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Appendix B: APHIS authorizations for field tests of events J101 and J163 alfalfa

1998 Field Trials	**2001 Field Trials**	**2002 Field Trials**
98-093-08n	01-009-04n	02-004-12n
	01-009-05n	02-004-13n
	01-009-08n	02-004-14n
1999 Field Trials	01-010-09n	02-004-15n
99-047-03n	01-011-03n	02-004-17n
	01-016-33n	02-007-08n
2000 Field Trials	01-017-08n	02-010-08n
00-040-10n	01-017-09n	02-010-09n
00-053-07n	01-029-12n	02-010-10n
00-053-14n	01-053-08n	02-010-11n
00-053-17n	01-058-09n	02-011-01n
00-055-03n	01-058-10n	02-011-02n
00-063-18n	01-080-05n	02-028-29n
00-069-04n	01-092-07n	02-028-30n
00-139-01n	01-092-08n	02-044-10n
00-139-02n	01-107-01n	02-044-11n
00-171-02n	01-108-09n	02-044-15n
00-182-04n	01-156-01n	02-046-16n
00-207-01n	01-159-01n	02-046-19n
00-243-06n	01-163-01n	02-046-22n
00-272-04n	01-163-02n	02-046-24n
	01-164-01n	02-046-25n
	01-164-02n	02-046-26n
	01-164-03n	02-051-11n
	01-164-04n	02-051-17n

01-164-05n
01-164-06n
01-164-07n
01-205-04n
01-205-05n
01-205-06n
01-211-06n
01-211-08n
01-211-09n
01-219-02n
01-236-03n
01-243-10n
01-275-02n

02-051-20n
02-051-21n
02-051-23n
02-051-24n
02-051-26n
02-051-27n
02-052-06n
02-053-04n
02-056-08n
02-056-12n
02-060-08n
02-060-09n
02-077-14n
02-077-22n
02-078-04n
02-084-19n

2002 Field Trials

02-093-09n
02-099-01n
02-105-04n
02-170-02n
02-193-02n
02-205-02n
02-206-01n
02-212-04n
02-212-05n
02-214-09n
02-220-16n

2003 Field Trials

03-021-15n
03-021-17n
03-021-18n
03-021-19n
03-021-21n
03-021-22n
03-021-23n
03-022-03n
03-022-04n
03-034-30n
03-043-09n

2003 Field Trials

03-325-01n
03-328-02n
03-345-01n
03-345-03n
03-350-01n

2004 Field Trials

04-005-01n
04-007-01n
04-013-02n

2002 Field Trials	2003 Field Trials	2004 Field Trials
02-247-07n	03-043-10n	04-030-10n
02-346-12n	03-052-19n	04-030-14n
02-346-14n	03-052-21n	04-036-02n
02-346-15n	03-062-03n	
02-346-16n	03-062-04n	
02-346-17n	03-098-02n	
02-346-18n	03-098-03n	
02-352-01n	03-098-04n	
02-352-02n	03-098-06n	
	03-121-05n	
	03-121-06n	
	03-184-03n	
	03-184-04n	
	03-184-05n	
	03-184-06n	
	03-191-01n	
	03-191-02n	
	03-191-03n	
	03-191-04n	
	03-191-05n	
	03-191-06n	
	03-202-10n	
	03-218-01n	
	03-247-01n	
	03-247-02n	
	03-247-04n	
	03-304-03n	
	03-304-04n	

2003 Field Trials

03-304-05n

03-310-02n

03-314-03n

03-318-04n

03-318-05n

03-324-01n

03-324-02n

Appendix C: Summary table of critical data submitted with petition 04-110-01p for alfalfa events J101 and J163

Molecular genetic characterization data	**Figure/ table number and page in petition**
Plasmid map of PV-MSHT4	Fig. III-1 p. 31
DNA insert diagram with restriction sites and predicted fragment sizes	Fig. V-1A p. 49, Fig. V-1B p. 50
Southern blots verifying intactness of insert, promoter, coding region, polyadenylation signal and gene copy number	Fig. V-2 p.51, Fig. V-3 p.52, Fig. V-4 p.53, Fig. V-5 p.54, Fig. V-6 p.55, Fig. V-7 p.56, Fig. V-8 p.57, Fig. V-10 p.59, Fig. V-11 p.60, Fig. V-12 p.61, Fig. V-13 p.62, Fig. V-14 p.63, Fig. V-15 p.64, Fig. V-16 p.65
Southern blots verifying stability of inheritance of the *epsps* gene over multiple generations	Fig. V-19 p.68
Western blot characterization of EPSPS protein in events J101 and J163	Fig. V-21 p.78, Fig. V-22 p.80, Fig. V-25 p.89, Fig. V-26 p.91
Statistical analysis of genetic segregation pattern of multiple generations of events J101 and J163	Table V-1, p.71

Agronomic characterization data	
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Appendix D. Determination of Non-regulated Status for Roundup Ready® Alfalfa Events J101 and J163

In response to a petition (designated 04-110-01p) from Monsanto Company and Forage Genetics International, APHIS has determined that genetically engineered alfalfa transformation events J101 and J163 and progeny derived from them will no longer be considered regulated articles under APHIS regulations at 7 CFR Part 340. Permits or acknowledged notifications that were previously required for environmental release, importation, or interstate movement under those regulations will no longer be required for J101 and J163 alfalfa and its progeny. Importation of seeds and other propagative material would still be subject to APHIS foreign quarantine notices at 7 CFR Part 319 and the Federal Seed Act regulations at 7 CFR Part 201. This determination is based on APHIS' analysis of field, greenhouse, and laboratory data and references provided in the petition and other relevant information as described in this environmental assessment that indicate that J101 and J163 will not pose a plant pest risk for the following reasons. (1) It exhibits no plant pathogenic properties—although a plant pathogen was used in the development of this alfalfa, these plants are not infected by this organism, nor do they contain genetic material from this pathogen that can cause plant disease. (2) It exhibits no characteristics that would cause it to be more weedy than the non-transgenic parent alfalfa line or other cultivated alfalfa. (3) Gene introgression from J101 and J163 to native, introduced, or naturalized species of *Medicago* in the United States is extremely unlikely, and it is not likely to increase the

weediness potential of any resulting progeny nor adversely effect genetic diversity any more than would introgression from other cultivated alfalfa. (4) Disease and insect susceptibility and compositional profiles of the plants of J101 and J163 are similar to those of its parent variety and other alfalfa cultivars grown in the United States, therefore, no direct or indirect plant pest effect on raw or processed plant commodities is expected. (5) Field observations, compositional analyses, and data on the safety of the engineered EPSPS protein all indicate that J101 and J163 should not have a greater potential than other cultivated alfalfa to damage or harm organisms beneficial to agriculture. (6) Compared to current alfalfa pest and weed management practices, cultivation of J101 and J163 should not reduce the ability to control pests and weeds in alfalfa or other crops. In addition to our finding of no plant pest risk, there will be no affect on threatened or endangered species resulting from a determination of non-regulated status for J101 and J163 and its progeny.

APHIS also has concluded that there may be new varieties bred from J101 and J163 alfalfa; however, they are unlikely to exhibit new plant pest properties, i.e., properties substantially different from any observed for alfalfa descended from J101 and J163, or those observed for other alfalfa varieties not considered regulated articles under 7 CFR Part 340.

John T. Turner
/s/ John T. Turner for Cindy Smith
Cindy Smith
Deputy Administrator
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Date: 6/14/05

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, et al., Defendants.	) Case No. C06-1075 CRB) DECLARATION OF PATRICK TRASK IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, Patrick Trask, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I reside at 18166 Smithville Road, Wasta, South Dakota 57791

3. I own Trask Family Seeds, and I have lived and worked on this farm for five decades. I have raised my twelve children on this farm, all of whom have worked on the farm and most still do. My family has raised alfalfa in South Dakota for four generations.

4. Trask Family Seeds raises South Dakota Common alfalfa seed and hay. South Dakota Common is a public variety of alfalfa that has been developed over generations by farmers in my region; it is not patented or trademarked. Western South Dakota is an important alfalfa seed growing region because the climate is suitable for the development of alfalfa seed.

5. Our farm raises alfalfa and alfalfa seed on 8500 deeded acres and 800 leased acres. By contract, I also

custom harvest alfalfa seed and hay off of twenty to thirty family properties within a 100 mile radius of my farm. I sell alfalfa seed all over the country.

6. In addition, I raise cattle on my land and keep approximately 850 head of beef cattle. We market our beef as all-natural.

7. The deregulation of alfalfa seed could lead to contamination of my alfalfa seed crops. Genetically engineered alfalfa seed can cross pollinate with and contaminate conventional alfalfa seed. With dry conditions where I live and the pollination by bees, the genetically engineered traits can travel three or four miles. With a perennial plant like alfalfa, any accidental genetic contamination will be irreversible.

8. When planted in my region, I am terrified by the prospect of contamination by genetically engineered alfalfa. Genetic contamination could result in the loss of public varieties, like South Dakota Common, which have certain traits that are beneficial to farmers. The loss of South Dakota Common would economically devastate Trask Family Seeds as it is our primary crop. In addition, it would greatly affect my aesthetic interests because I have a generational connection to the land and the South Dakota Common seed.

9. The United States Department of Agriculture ("USDA") has failed to fully consider the potential impacts of deregulating genetically engineered alfalfa. Permitting growers to plant genetically engineered alfalfa will result in contamination of feral and domesticated alfalfa. USDA ignored the plant contamination issue and the reproductive elimination of conventional alfalfa. The decision turns a blind eye to alfalfa seed, hay, and honey farmers who want to keep

South Dakota Common and other public varieties of alfalfa free of genetic contamination. USDA has not provided any mitigation measures to reduce or eliminate genetic contamination. Farmers, who do not grow genetically engineered alfalfa, bear all of the risk and responsibility for genetic contamination. There is no requirement for farmers who grow genetically engineered crops to ensure they do not contaminate nearby fields.

10. Genetically engineered alfalfa will also result in increased use of glyphosate and lead to the development of glyphosate resistant "superweeds." Consequently, the effectiveness of glyphosate will decrease. I know corn and bean farmers who, after planting Roundup Ready corn and soybeans, increased their use of glyphosate and saw Roundup-resistant weeds develop in their crops. The spread of these herbicide-resistant "superweeds" onto my land would make it more difficult and expensive for me to control weeds in my alfalfa crops. Currently, my alfalfa crops require very little chemical weed control, but the spread of superweeds would likely increase the amount and toxicity of chemicals that I would need to apply to my crops.

11. I am concerned that the Canadian Thistle, which is a problem weed in Western South Dakota, will become more resistant to glyphosate. Glyphosate resistant superweeds will result in the increased use of other herbicides such as Tordon and 2,4 D, both of which are more toxic than glyphosate, and much more dangerous to apply. As a conventional farmer, who uses pesticides as part of my farming practices, I am very concerned about the loss of effectiveness of glyphosate due to increased weed resistance. I want to

avoid the use of and exposure to more dangerous pesticides.

12. The USDA did not address the issue of increased weed resistance resulting from the deregulation decision and the resulting environmental effects.

13. I led an unsuccessful effort to have the state Secretary of Agriculture to ban Roundup Ready alfalfa in South Dakota. The Secretary of Agriculture eventually relied on the USDA deregulation determination as a reason to not ban Roundup Ready alfalfa. The deregulation determination will be directly responsible for contaminating the South Dakota common seed. The deregulation determination adversely affects my economic, recreational, and aesthetic interests.

14. The USDA's decision to deregulate genetically engineered alfalfa has caused and will continue to cause economic harm to my farming business.

15. For my hay business, genetically engineered alfalfa contamination will make the hay market less stable. Certain other countries are committed to avoiding genetically engineered crops. If producers who sell their crops internationally have genetic contamination, they will likely try to sell the product domestically. Increasing the domestic supply of hay will force down domestic prices.

16. The USDA's failure to consider the environmental consequences of deregulating genetically engineered alfalfa and to make public information on seed contamination and weed resistance will cause environmental harm to my crops and those in my region. Seed contamination and weed resistance

problems will cause economic harm to my farming businesses.

17. My customers do not want to purchase contaminated alfalfa seed because they are concerned about lawsuits. There have been a few high-profile lawsuits where farmers have been sued for having patented seeds growing in their fields. My customers do not want to face liability after planting alfalfa seeds contaminated with genetically engineered, patented seeds. To ensure that my seeds are pure, I will need to test my crops and obtain certification that my seeds are free of genetically engineered alfalfa. Genetic testing will add both administrative and lab expenses to my seed business.

18. My cattle business will also be affected by the spread of genetically engineered alfalfa crops. Customers are willing to pay more for all-natural beef. While I currently market my cattle as all-natural, I cannot credibly make this claim if my cattle feed is contaminated with genetically engineered alfalfa.

19. Because I custom harvest alfalfa crops throughout western South Dakota, I am especially concerned about the potential for contamination. The producers I harvest for do not want genetically engineered alfalfa in their fields. If any of the fields I harvest become contaminated, then my combine will pick up genetically engineered seed and can spread the seed to other fields I harvest and the seed cleaning businesses with which I work. You cannot clean all of the seeds from the combine; some of the seeds will be transported into other fields. I harvest from fields about 100 miles away in all directions. My combine could transport genetically engineered alfalfa seed

from a contaminated field into another field many miles away.

20. I have been and will continue to be aesthetically injured by the government's failure to adequately consider the contamination problems associated with genetically engineered alfalfa.

21. As a consumer of the alfalfa, cattle, and honey grown on my farm, I am concerned that genetically engineered alfalfa will contaminate my foods. I try to avoid genetically engineered foods and feel that conventional foods are more natural and healthy. Genetically engineered foods have different nutrient compositions. For instance, genetically engineered alfalfa contains more fiber and less protein that conventional alfalfa. The deregulation of genetically engineered alfalfa could make it impossible for me to grow and eat genetically pure foods and will increase the costs of maintaining a diet free of genetically engineered foods.

22. I have a strong religious faith and believe that humans should strive to do no harm in the natural world God created. Recently, I have learned a great deal about genetic engineering. Although I had originally believed that USDA would only deregulate plants which had negligible or reversible effects, I believe that USDA has not conducted enough tests on genetically engineered crops to be sure that they will not cause health problems. When there is no reason to change a good thing, it is better left alone.

23. I understand that genetic engineering alters the protein structure in plants. Alfalfa's high protein content makes it a great forage source for cattle. Genetically engineered alfalfa contains less protein than conventional alfalfa. Proteins are the fundamental

building blocks of life. My friends who winter their cattle in fields in Nebraska noticed that cattle preferred to eat conventional corn crops and left the genetically engineered corn standing. Cattle who ate conventional corn thrived, while cattle who ate genetically engineered corn grew slower than expected.

24. I was injured by the USDA's failure to conduct a full environmental review and make the information public. The decision to deregulate genetically engineered alfalfa will have serious environmental effects. The public should be aware of these effects and have the opportunity to participate in the decision.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on _____, 2006, in Wasta, SD.

_____/s/_____

Patrick Trask

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.	) No. C06-1075 CRB
Plaintiffs,	) DECLARATION OF CHARLES M. BENBROOK IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT
vs.	
MIKE JOHANNS, et al.	
Defendants.	

I, Charles M. Benbrook, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I reside at 90063 Troy Road, Enterprise, Oregon 97828 and I am not a party to this action.

3. Currently, I am president of Benbrook Consulting Services, a consulting business that provides services to domestic and international clients in the areas of agricultural technology, policy, food safety, and environmental quality. Areas of work include biotechnology, pesticide use, risk and regulation, and adoption and cost-benefits of Integrated Pest Management strategies.

4. Prior to my consulting business I served as Executive Director of the Board of Agriculture of the National Research Council/National Academy of Sciences. During my tenure at the NRC, I oversaw and carried out a number of National Academy of

Sciences reports covering such topics as the unique risks faced by infants and children from pesticides exposure, the modernization of U.S. pesticide regulatory law, pesticide use and resistance, and the applications of genetic engineering.

5. Prior to NRC, I worked as staff director for Subcommittee on Department Operations, Research and Foreign Agriculture, Committee of Agriculture, U.S. House of Representatives and as Agricultural Policy Analysts for the Council on Environmental Quality, Executive Office of the President.

6. I hold a BA in Economics from Harvard University and MA and PhD in Agricultural Economics from the University of Wisconsin. I have authored numerous peer-reviewed articles on the subject of pest management systems, technology, and risks. My full *curriculum vitae* is attached herein as Attachment A.

7. Over the last several years as part of my consulting work I have studied in detail the use patterns of herbicides and insecticides associated with the introduction of genetically engineered crops. This work has included in-depth study and analyses of the use of herbicides linked to herbicide-tolerant, GE crops, including glyphosate (often marketed under the trade name Roundup). This work led to the release of a report entitled *Genetically Engineered Crops and Pesticide Use in the United States; The First Nine Years* (2004). This study is provided as Attachment B.

8. In completing the analysis contained in *The First Nine Years* I relied on data from several sources. USDA's National Agricultural Statistic Service (NASS) pesticide use data for the years between 1996 and 2004 was the major source of crop-specific data. The annual NASS survey on pesticide use in major

field crops is the best and only publicly accessible national data on pesticide use. I also used data concerning the acreage planted of the three major commercially used genetically engineered crops (corn, soybeans and cotton) from the USDA's Economic Research Service.

9. *The First Nine Years* analyzes the herbicide and insecticide use patterns associated with the commercial introduction of two types of genetically engineered crops. It covers 1996 through the year 2004. One group of crops included in the study was genetically engineered to be resistant to application of specific herbicides. Over the time period covered in the report, genetically engineered herbicide tolerant crops were rapidly adopted. Acres planted to herbicide-tolerant GE varieties totaled approximately 487 million acres from 1996-2004 and consisted of about 73% of all acreage planted to GE crops. The vast majority of these genetically engineered herbicide-tolerant crops are engineered to tolerate the application of the herbicide glyphosate (RoundUp).

10. *The First Nine Years* undertakes a three step process in estimating the impacts of herbicide-tolerant crops on total herbicide use. First, using USDA data, the acreage producing herbicide tolerant crops is estimated. Second, the average pounds of herbicide per acre on conventional acreage (i.e. not genetically engineered) are compared to the average pounds per acre applied on the genetically engineered herbicide-tolerant crop. The differential between these two figures is then calculated. Third, the differential between the pounds per acre of herbicide applied to the genetically engineered herbicide-tolerant crop each year is multiplied by the acres planted to genetically

engineered herbicide tolerant crops each year. The differences over each of the nine years are then added to produce an estimate of the total impact of genetically engineered herbicide-tolerant crops on herbicide use.

11. The analysis found that for genetically engineered herbicide-tolerant crops, the first two years of commercial use resulted in a moderate reduction of in herbicide use, however, by the fourth year of use the amount of herbicide used with the genetically engineered herbicide-tolerant crops began to rise significantly.

12. The final analysis in *The First Nine Years* found that the use of genetically engineered herbicide-tolerant crops have increased herbicide use by 138 million pounds compared to conventional crops since their commercial introduction in 1996. This represents about a 5% increase across the three major genetically engineered herbicide-tolerant crops - corn, soybeans and cotton. For one crop, herbicide tolerant soybeans, the analysis found that over the nine-year period 117 million more pounds of herbicide had been applied. Indeed, USDA data shows a clear upward trend in glyphosate and herbicide-tolerant herbicide rates per acre since 2001.

13. Among the reasons for the increase in the average applications herbicides on GE crops has been the development of weeds resistant, or less sensitive to the application of glyphosate. Resistance to glyphosate has emerged as a serious concern throughout intensively farmed areas in the United States. As more glyphosate resistant crops are introduced, the selection pressure for weeds to develop resistance to glyphosate continues to increase. As the effectiveness of glyphosate has fallen, farmers have had to apply

more glyphosate and additional herbicides beyond glyphosate to obtain the same level of weed control.

14. The commercial introduction of genetically engineered glyphosate-resistant alfalfa will only serve to exacerbate this problem, given the fact that herbicide tolerant alfalfa, cotton, corn, and soybeans will be produced in many of the same areas. An upward trend in total herbicide use on alfalfa is bound to emerge if substantial acreage is planted to herbicide-tolerant varieties. This would be a significant shift from the way alfalfa is currently grown. Alfalfa is currently grown using relatively few herbicides compared to soybeans, corn and cotton.

15. Many regions grow and export substantial volumes of alfalfa hay to countries that prohibit the planting of all or most GE crops. Buyers in Japan are willing to pay top dollar for the very high quality hay coming out of several western production areas; most of these markets will be lost if herbicide-tolerant alfalfa is widely planted.

16. High quality alfalfa is the backbone of the rapidly growing organic dairy and beef industries. USDA organic production standards prohibit the feeding of any genetically engineered feeds to livestock producing organic dairy or meat products. Given the propensity of pollen to flow from one alfalfa field to the next, the risk of gene flow into nearby conventional fields, including fields under organic management, is high. At a minimum, this will impose new testing costs on organic alfalfa growers and livestock farm operators. If gene flow proves as rapid and pervasive as it has in canola, the planting of herbicide-tolerant alfalfa will almost certainly curtail the growth of this profitable segment of the agricultural sector.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on _____, 2006, in Enterprise, Oregon.

_____/s/_____
Charles M. Benbrook, PhD

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

[1] UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.	)
Plaintiffs,	)
vs.	) No. C 06-1075 CRB
MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al.,	)
Defendants.	)

San Francisco, California
Friday, January 19, 2007

REPORTER'S TRANSCRIPT OF PROCEEDINGS

* * *

PROCEEDINGS

THE CLERK: Calling case C 06-1075, Geertson Farms versus Mike Johanns.

Appearances, Counsel.

MR. ROSTOV: Good morning, Your Honor.

* * *

[4] or could make a difference in this particular case.

So those are two questions I have. Maybe others will occur to me as we go on.

Also, I was curious as to what's happened. Is the product out there? Nobody asked me to enjoin anything. That's fine with me.

But, usually, you know, the threat of harm is such that if the plaintiffs are to be believed, one would think that a request for an injunction would come. But maybe that's not true in this case, since I don't know what's happening.

So you have to sort of tell me what's happening in the real world out there, and then talk about this.

MR. ROSTOV: Your Honor, we would like an injunction, and we hope to win the summary judgment so you would impose one.

THE COURT: Is it being introduced?

MR. ROSTOV: It's been deregulated, and we know that on a small scale it's been to seed in some areas, and we are very concerned about it. But the new planting season is in the spring, so we believe if we can resolve this now we can stop the next planting season.

THE COURT: Well, and I'll hear from the government, obviously. Why don't you go ahead and answer some of my questions and educate me.

MR. ROSTOV: Okay. Your Honor, like you, I also

* * *

[15] MR. ROSTOV: Exactly.

THE COURT: And the GE replace non-GE and maybe in the conventional farm —

MR. ROSTOV: Right.

THE COURT: —you're saying that the impact, all of which, by the way, hasn't in a sense been studied by the agriculture department.

MR. ROSTOV: Exactly.

THE COURT: And, therefore, that is a further justification for environmental impact.

MR. ROSTOV: Right. Because it's an uncertainty. And—exactly.

THE COURT: Maybe I should hear from the government a bit on these issues.

I'm really focusing on NEPA, because it seems to me that if I decide NEPA in favor of the plaintiffs, then I don't have to decide anything else. Do I?

MR. ROSTOV: We'd like you—

THE COURT: Well, I don't have to decide ten things; if I decide the NEPA thing, that's it.

MR. ROSTOV: Right.

THE COURT: This is a busy court, you know. I go home every night and I have a whole list of things to decide. So what I try to do is, I decide that which I have to and postpone for another day.

***

[17] briefs on the merits. Would you like—

THE COURT: They definitely have standing. All the alfalfa farmers seem to—why don't they have standing?

MR. PAGE: Your Honor, some very basic reasons. The Court talked about economic harm to organic farmers.

THE COURT: Really?

MR. PAGE: Under the Ashley Creek case, economic harm under NEPA is not enough. NEPA is an environmental statute—

THE COURT: Let's say this wipes out organic farming. Let's just say that it's going to wipe it out. There's going to be no more organic farms. You say that's not enough? Is that what you're telling me?

MR. PAGE: Your Honor, the Ashley—

THE COURT: And then it goes in—the organic farms go to the cows, and then the cows—the cows eat the genetically-enhanced alfalfa; and, therefore, that's the end of the organic wheat business. And then the milk that comes out is genetically affected, and that's the end of the dairy business.

And the United States government Department of Agriculture wants me to take the position that that's not enough for an environmental impact.

I want to think about that. Is that your argument?

MR. PAGE: Your Honor, yes.

* * *

[21] glyphosate. That's their reproduction argument. But the government would like to, with all of these briefs, simply summarize its evidentiary case for the Court now before finishing standing.

THE COURT: Well, okay. Let's assume there's standing. Let's assume there's standing.

Are they wrong when they say that if you have a genetically-engineered alfalfa field adjacent, within a mile of a nongenetically-engineered alfalfa field, that through the process of pollination the nongenetically—that the alfalfa field without the genetically-engineered

alfalfa will be affected? Are they wrong in that statement?

MR. PAGE: Yes, Your Honor, they are very wrong for, basically, two evidentiary reasons.

The first is, is that APHIS, as the Court knows, is a highly specialized scientific technical agency that Congress created to regulate issues like these.

In the record, one line of evidence and one related evidentiary failure by plaintiffs is clear. Plaintiffs have not rebutted APHIS's scientific determination that the engineered gene and corresponding enzyme is identical in all relevant biological respects. Two, gene and enzyme in nature that is both common in nature and harmless in nature, because it is present in bioorganisms, including microorganisms living in common soil, and also common green plants.

* * *

[24] determination that this engineered gene and corresponding enzyme is identical in all relevant biological respects to the gene and enzyme that it is in common soils, common bacteria that live in common soils and common green plants.

They also have not shown any theory by which the EPA and FDA safety tolerances would be ineffective in protecting the environment.

And, indeed, when you look at their declarations, Your Honor, they do not even compare glyphosate residues that would be on the alfalfa used in this case with the glyphosate residue maximums that are mandatorily enforced by EPA and FDA.

But the Court also had some questions about the factors of the merits. And we would like to start with NEPA and then move to the Endangered Species Act

and Plant Protection Act, unless the Court still has questions about standing.

THE COURT: Go ahead.

MR. PAGE: Now, under NEPA, Your Honor, we think that -- again, in all of this voluminous briefing it would be beneficial to this Court for the government to provide it with two cases that summarized the government's NEPA arguments. Those cases would be the Kleppe Supreme Court case at 427 U.S. 390, 394, 399, 412 to 414. Again, 427 U.S. 390. That's Kleppe.

And the Ninth Circuit case recent, Native Ecosystems

* * *

[31] require harvesting to occur before mature seeds develop, then any reproduction between nonengineered alfalfa and challenged alfalfa, even if it is successful, would not subsequently be successful in the future.

In other words, there would be no successful reproduction in the future because it would occur—the plants lacking seeds could not affect it. So, in other words, because the plants would lack seeds, even if they were fertilized, one cultivated nonengineered alfalfa and one engineered alfalfa strand or field, even if fertilization was successful, it could not continue into the future because the plants would lack seeds. Okay.

But plaintiffs observe correctly, Your Honor, that if these harvesting practices aren't followed—and, certainly, there aren't EPA or APHIS inspectors ordering farmers to use the preferred harvesting practices—it's possible, and APHIS found this, doesn't deny it in the record—

THE COURT: The harvesting, when you start to harvest, there are a lot of factors that have to be considered, not the least of which is the weather.

MR. PAGE: That's right.

THE COURT: And it may be that weather conditions, and so forth, don't permit the type of harvesting that would then comply with the government's theory that you could harvest **[32]** at a particular time and, thereby, avoid the reproduction.

MR. PAGE: That's right.

THE COURT: So, I mean, it's sort of like, yeah, maybe they can to it if they can control all the variables. But nobody can control the weather, and so that's an uncertainty. And when it operates as an uncertainty, it could very well thwart the government's injunction to get out there early in the morning and chop off your alfalfa seeds, or whatever it is.

MR. PAGE: That's correct, Your Honor. Absolutely correct. And that's the reason why.

And the final part of this argument about reproduction and the assertion by plaintiffs that would be environmentally significant, has a scenario in which APHIS found in the EA and FONSI that bee pollination could occur within two months of the challenged alfalfa, has a situation, Your Honor, in which APHIS again adopts detailed findings in which it concluded that even if this kind of reproduction by bees does occur, it would be environmentally insignificant.

And let me explain exactly what APHIS said. APHIS stated that any reproduction between engineered and nonengineered alfalfa would lack the, quote, biological significance, because the challenged alfalfa's engineered gene and its corresponding enzyme

are, quote, not toxic or pathogenic. That's the first finding. Also, identical in all

* * *

[37] factors.

And the government has made an argument that NEPA did not require it to consider the socioeconomic impacts because there are no physical threats documented in this record. But we also wanted to take something that was in a footnote, and give it to the Court more firmly.

The APHIS did consider the socioeconomic impacts to farmers, organic and otherwise. And that's in AR 5510 to 5512, 5510 to 5512. And by that, under those citations to the record, Your Honor, we would argue that APHIS exceeded its obligation to consider social and economic dislocations.

THE COURT: Thank you. Let's take a 5-minute recess.

(Recess.)

THE COURT: This is what I propose, that you come back this afternoon to respond to these arguments. I want to give everybody a fair hearing here. And when I say "fair," I mean as complete as possible.

The government has raised, I think, a fairly comprehensive laundry list of responses to the plaintiffs' argument, and I want to be sure that the plaintiffs have their full day in court, because of the consequences of a decision one way or the other.

And I would like the plaintiffs to tell me, as I was listening to this, whether the fact that the introduction of [38] the genetically-engineered alfalfa could arguably change or modify the nongenetically-

engineered alfalfa, whether that in and of itself, without more, would justify an environmental impact assessment.

That is, if you simply—because the government may concede, though they probably are not going to, but I don't know that they wouldn't have to concede that there would be some modification, or potentially could be some modification of the nongenetically-engineered alfalfa, maybe to the extent of wiping it out, no more will there be nongenetically-engineered alfalfa, there will all be modified alfalfa. Some will be modified less than others, I guess, or maybe stronger or weaker. I don't know. But does that in and of itself justify a harder—what I call a harder look, that is the environmental impact assessment?

So I would like the plaintiffs to respond to that, and then I'll hear from the government on that issue, as well. Okay. So we'll resume at 2 o'clock.

MR. ROSTOV: Thank you, Your Honor.

THE COURT: Thank you.

(Recess in proceedings from 11:48 a.m. to 2:00 p.m.)

THE CLERK: Calling case C06-1075, Geertson Farms versus Mike Johanns.

Appearance, Counsel.

* * *

[51] Putting aside the standing issue, it's your view that even if it eliminates all organic alfalfa, no—a FONSI would be appropriate, even if it wipes it out?

MR. PAGE: Yes, Your Honor. The view is, is that unless wiping it out would precipitate a significant environmental effect on water, air, soils or species, it's not cognizable under NEPA—

THE COURT: Yeah, but how would we know that if you haven't done any study at all?

MR. PAGE: Your Honor, the case moved, I guess, in a sense, in this hearing somewhat fast. We appreciate how much time you have already devoted to it.

But there's a shorthand tendency that plaintiffs make of just talking about FONSI. But, indeed, the environmental assessment that substantiates the FONSI is a small environmental impact statement. The only reason why it is not as lengthy under the regulations as an EIS is simply that an EIS takes one to two years.

So under the statute and under the regulations, an environmental assessment is the document you prepare to determine whether or not the environmental impact is significant enough to merit an EIS.

But because it is still—from listening to plaintiffs just now, they are still unable to show a significant effect on the physical environment, again, water,

* * *

[53] environmental—a significant environmental impact, the elimination of all organic alfalfa.

MR. PAGE: Yes, Your Honor. But there are two parts, obviously, of our response. The first is, is that let's assume that all plaintiffs have done here is show that if all organically-grown alfalfa is now tainted because it has this engineered gene in it that actually restores the natural process that used to exist before glyphosate, somehow—

THE COURT: You're saying that's good?

MR. PAGE: Yeah, that somehow that would eliminate the industry. Let's just assume that's true and that they've showed harm. I wanted to emphasize the Ashley Creek case again, and that's 420 F.3d, at page 940, Your Honor.

Here's what the Ninth Circuit says about economic interests: "The purpose of NEPA is to protect the environment, not the economic interests of those adversely affected by agency decisions. Accordingly, we, the Ninth Circuit, have consistently held that purely economic interests do not fall within NEPA's zone of interest. Plaintiff who asserts"—

THE COURT: They will say that. They will say, fine, we're not going around saying all the organic farmers are going to file Chapter 13 proceedings. They're saying, before you even get there, you've now eliminated a particular natural plant.

* * *

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	NO. C 06-01075 CRB DECLARATION OF JERRY TLUCEK

I, Jerry Tlucek, declare;

1. I operate a dairy farm in Melba, Idaho. We have 2000 dairy cows and 2500 acres of irrigated farmland. On that acreage we grow feed crops and all of the forage for our dairy operation. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. I currently have 1100 acres devoted to alfalfa. We first planted Roundup Ready Alfalfa ("RRA") in the summer of 2005, starting with 40 acres. I chose to plant RRA because of its improved weed control, which in turn results in increased forage quality. Better quality forage results in greater production from my dairy cows.

3. The results from the first 40 acres for RRA have been fabulous. I have achieved much greater yield than I have ever achieved from conventional alfalfa. I believe I can sustain the crop for a year longer than is usual for conventional alfalfa, and go four years without any significant reduction in yield and

quality. In 2006, I planted 200 more acres of RRA and in 2007 I plan to plant an additional 250 acres.

4. I have signed the Monsanto Technology/ Stewardship Agreement and I am familiar with the requirements of Monsanto Technology Use Guide, including the requirement for harvest at or before 10% bloom. I do five cuttings per year and, in any event, always adhere to that requirement as that is when the crop is at its greatest feed value—once the crop starts blooming, protein starts to deteriorate very rapidly. I have been farming for 50 years end cannot recall ever being prevented by weather or otherwise from harvesting my alfalfa on time.

5. If I were forced to stop using RRA or to plow under my RRA fields, it would have a significant impact on my operations. Not only would I lose the value of the RRA forage (which I estimate at $36,000 for the 240 acres currently planted and an additional $37,500 for the 250 acres we plan to plant this year), but production from my dairy would be reduced as well.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 1st day of March 2007 at Melba, Idaho.

/s/ Jerry Tlucek
JERRY TLUCEK

Stewardship Program for Gene Flow Management in Roundup Ready® Alfalfa Production

Monsanto and Forage Genetics Inc. (FGI) have jointly developed Roundup Ready® alfalfa for commercial forage production in the United States. Prior to the introduction of Roundup Ready alfalfa (RRA) to U.S. alfalfa producers, Monsanto and FGI developed a stewardship plan that included application for securing regulatory approvals in key U.S. alfalfa hay export markets, implementation of hay and seed production practices designed to facilitate co-existence of both Roundup Ready and conventional alfalfa hay and seed[1,2,3] and a commitment to continued dialogue with stakeholders in the alfalfa forage and seed production industry.

KEY ELEMENTS OF TRAIT STEWARDSHIP

- *Licensing, contracting and pesticide registration:* Under terms of the Monsanto Technology/Stewardship Agreement (MTA) RRA may only be used to produce forage for feed uses. Seed production of RRA requires an additional and specific seed production contract from FGI or an FGI authorized FGI seed contractor. FGI is the sole Monsanto licensed seed producer. Although Roundup herbicide is broadly registered for RRA forage production purposes in the U.S., Roundup herbicide is labeled for seed production purposes in only certain states. Unregistered pesticide use and unlicensed commercial harvest, sale or uses of

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® Roundup Ready and Roundup are registered trademarks of Monsanto Technology LLC

patent protected seed are violations of state and federal laws.

- *Seed channel management:* All RRA seed is packaged with a unique purple seed coating and "Roundup Ready alfalfa" seed-bag labeling. RRA seed can only be sold by variety name. All seed purchasers, dealers, distributors, producers and processors of Roundup Ready seed must be licensed by Monsanto and agree to trait stewardship appropriate to their activities. Monsanto conducts an annual audit to insure seed channel compliance to these stewardship requirements.
- *Industry tools:* To support buyer-seller agreements that may stipulate conditions for biotech trait status, simple to use trait detection strips are readily available for alfalfa seed and hay product use (e.g., Strategic Diagnostics, Inc., Envirologix, Inc.).

MITIGATION OF POLLEN-MEDIATED GENE FLOW

Gene flow between populations is a natural occurrence in all cross-pollinated crops. Alfalfa requires specific bee pollinators for cross-pollination; it is not wind pollinated. In alfalfa, the potential for Roundup Ready gene flow between fields is significantly constrained (limited) by crop and bee pollinator biology, typical alfalfa grower practices, and numerous additional grower practices required in the Monsanto license for forage growers and Forage Genetics required best practices for contracted RRA seed growers as follows.

I. **Hay-to-hay field gene flow**

In alfalfa, forage producers cut hay at regular intervals prior to or near early bloom for optimum forage quality and yield. Forage quality of the crop deteriorates rapidly after this stage of crop maturity. The potential for pollen-mediated hay-to-hay field gene flow has been thoroughly discussed in a recent University of California publication[4] wherein it is stated that, "...the likelihood of AP [adventitious presence] occurring between hay fields becomes infinitely small, likely to be far less than 0.001% of field biomass even under high estimates. The combination of frequent harvests, lack of significant flowering, lack of significant seed production, and the highly competitive and allelopathic nature of alfalfa that prevents ready germination of alfalfa seeds in existing fields should prevent most if not all gene transfer".

II. **Hay-to-seed field gene flow**

Alfalfa hay is planted in every state in the U.S. Intermingled alfalfa hay and alfalfa seed production only occurs in a few western states which have the specific climate required for successful commercial production. Certified alfalfa seed production requires isolation from hay production of another variety. The isolation is inspected and verified by state seed certification organizations or an accredited organic certifier. Although non-certified seed is not officially regulated, in areas where common (e.g. non-certified) seed production is intermingled with RRA forage production, RRA forage growers are required to harvest at or before 10% bloom[3]. Seed

producers and regulators recognize that genetic purity of the seed is related to physical isolation between the seed field and outside sources of pollen. For reasons explained above, due to sparse and short-term flowering, Roundup Ready forage fields are an unlikely source of pollen or pollinators. Hay-to-seed gene flow research has been conducted and data is publicly available[1,2]. Bees were applied to pollinate the seed fields in these studies, and, during the midsummer pollination period, the hay field plots were intentionally allowed to flower more extensively than is typical for forage: i.e., 50% bloom in 2000[1,2] and 20% bloom in 2006. Therefore, the hay field gene sources were representative of delayed or poorly managed hay fields growing close to a seed field. Under these conditions, gene flow into the seed field was very low (0.2%) at 150-300 ft and, it was rarely detected (0.00 to 0.05%) at distances greater than 350 ft. These studies represent "worst case" forage management. Forage producers who plant Roundup Ready Alfalfa seed will very likely cut hay more aggressively to manage for optimum forage quality and minimize the number of open flowers on the standing hay. Conventional seed producers can use reasonable seed field isolation distances from neighboring alfalfa fields and certified identity preserved best management practices (such as organic certification) to effectively manage AP in conventional seed tracing to RRA hay production. In the western U.S. where hay and seed are both produced, Monsanto requires and collects field

location data for all planting of Roundup Ready alfalfa.

III. Seed-to-seed field gene flow

Certified alfalfa seed must be produced using production methods and isolation defined and verified by state seed certification organizations or an accredited organic certifier. Non-certified seed is not officially regulated. Forage Genetics requires that all contracted RRA seed growers and conditioners follow FGI best practices policies for Roundup Ready trait stewardship. These best practices, implemented to maintain high seed quality in FGI seed and facilitate coexistence with non-GMO seed/hay producers; are based on industry experience and gene flow research data; and have proven to be effective strategies for managing AP. It is well documented that isolation is one of the effective measures to mitigate pollen flow to very low levels[1,2,5,6] and that bee species differ in their potential to effect gene flow[1, 2, 5, 6, 7]. FGI and its contractors use process-based best practices for Certified Seed production that meet or exceed the more stringent principles of AOSCA Foundation Class alfalfa seed production standards. Likewise, other producers of conventional and or specialty quality alfalfa seeds independently implement various production strategies to assure their company's product quality claims. Research data is available to the industry so that all seed producers can use the information to effectively manage seed quality[2, 5, 6].

FGI mandated Best Practices for RRA seed producers include: (1) All RRA seed is produced

only in specified Western states and meets or exceeds AOSCA and/or OECD certification standards; (2) At planting, all RRA seed fields require, at minimum, a foundation class isolation distance to existing conventional (i.e. non biotech) seed fields: RRA eligible fields have 900 ft, 1 mile or 3 miles isolation for leafcutter bees, alkali bees or honeybees, respectively. This isolation distance is 5x–85x, depending on pollinator, the requirement for certified seed of conventional varieties and is verified by the appropriate state seed certifying agency; (3) Seed growers must follow FGI's strict equipment sanitation, pollinator management and seed handling requirements; and (4) the planting date, location distance, field size, variety name and termination date for all RRA seed production fields are reported to and inspected by the state's seed certifying agency to facilitate the industry's management of field history and seed field isolation information. FGI field staff monitor seed grower compliance to these best practices.

REFERENCES

1. USDA Petition for Deregulation: http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf.
2. Forage Genetics' stewardship policies and pollen flow research data: http://foragegenetics.com/News.asp
3. Monsanto Technology Use Guide and Monsanto Technology/Stewardship Agreement (1-800-ROUNDUP).

4. Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf
5. Teuber, L.R., et al. 2004. Gene flow in alfalfa under honeybee (*Apis mellifera*) pollination (Abstract). 39th NAAIC http://naaic.org/Meetings/National/2004NAAIC&TC/2004abstracts/lteuber.pdf
6. Teuber, L.R., et al. 2005. Gene flow in alfalfa (*Medicago sativa L.*) when honeybees (*Apis mellifera*) are used as pollinators (Abstract). NCWSS http://www.ncwss.org/
7. Crane, J.H. 2002. Pollinating bees of U.S. alfalfa compared for rates of pod and seed set. J. Econ. Entomol. 95:22-27.

[Logo omitted] Forage Genetics International

PROPRIETARY SEED SERVICES AGREEMENT FOR THE PRODUCTION OF ROUNDUP READY® ALFALFA SEED

THIS AGREEMENT, made this _____ day of _____, 2007, by and between Forage Genetics Inc., a subsidiary of Land O'Lakes, Inc., a Minnesota cooperative with its principal place of business in Minneapolis, Minnesota and doing business as Forage Genetics International (hereinafter "FGI") and _____ _____ (hereinafter "Grower").

WHEREAS, FGI is the owner of certain proprietary Roundup Ready alfalfa varieties, and desires Grower to perform certain services relating to the production of such seed; and,

WHEREAS, Grower has the capability and facilities to perform services relating to the production of quantities of seed and desires to perform such services for FGI; and

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, the parties agree as follows:

1. **Acreage Description and Duration**. The Grower agrees to plant on land of which he is in possession as owner/renter, the variety of FGI proprietary seed described below on the acreage described below. Upon the expiration of this Agreement, the Grower shall take such actions as are necessary to prevent any future growth, harvest or survival of the alfalfa. Stand destruction must occur prior to first flower in subsequent year.

Production year(s): | | | |

	Field name	Acres	Field Location: Town-Range-Section & County	Latitude / Longitude (GPS Coordinate)	Previous crop(s)	Distance, direction and contractor of nearest conventional seed field

Total no. acres this contract:		Main pollinating bee to be used for this contract: _____ (state one of the following: leafcutter, alkali or honey bee)	
Variety of Seed* (Experimental Variety)			*Seed is FGI proprietary Roundup Ready alfalfa seed variety and contains proprietary germplasm and patented traits.
Stock seed	Lot no.:	Class:	Approximate Seedling population per acre

Contracted pounds: All seed produced from the above acreage is property of FGI and Grower agrees to deliver all seed. **The Grower agrees that he will, at his sole expense and responsibility:** properly prepare the soil, plant, irrigate, pollinate, harvest, control weeds, cultivate and maintain the growing crop as necessary in order to produce the seed crop; and upon contract termination ensure thorough stand take-out, control alfalfa volunteers, and notify FGI as to the date and method used to terminate the stand. Grower agrees to allow FGI or FGI designee access to inspect all grower fields and records resulting from the fields described above.

2. **Stock seed**. The parties agree that FGI shall provide the stock seed named above, with a guaranteed Roundup Ready Trait purity of greater than or equal to 90%, to Grower at a cost of $10.00 / lb on raw seed basis, fees to be deducted from first years' crop payment. The parties expressly agree that the Grower's use of FGI's stock seed does not constitute a sale of such stock seed to the Grower by FGI. Grower agrees that the stock seed described herein shall only be utilized on the acreage described above.

   THE PARTIES EXPRESSLY AGREE THAT THE STOCK SEED AND ANY SEED PRODUCED FROM SUCH STOCK SEED IS THE SOLE AND EXCLUSIVE PROPERTY OF FGI. EXCEPT FOR MONSANTO'S THIRD-PARTY RIGHTS ACKNOWLEDGED BELOW, NOTHING HEREIN NOR THE OPERATION OF LAW, SHALL GRANT TO GROWER OR ANY OTHER THIRD PARTY ANY RIGHT, TITLE OR INTEREST IN OR TO THE STOCK

SEED OR ANY SEED PRODUCED FROM SUCH STOCK SEED. GROWER'S SOLE RIGHTS UNDER THIS AGREEMENT ARE FOR PAYMENT FOR SERVICES PROVIDED. The Grower shall not sell, assign, transfer, or otherwise allow to pass from his possession, any portion of the stock seed or resulting crop. UNAUTHORIZED PROPAGATION OR SALE OF PROPRIETARY SEED IS PROHIBITED. IN THE EVENT OF UNAUTHORIZED PROPAGATION OR SALE OF PROPRIETARY SEED OR PATENT-PROTECTED PROPERTY, FGI SHALL BE ENTITLED TO SEEK MONETARY COMPENSATION AS WELL AS INJUNCTIVE RELIEF FROM THE GROWER. Only unopened stock seed packages may be returned for refund, unused seed in opened packages must be disposed of within boundaries of fields planted unless other arrangements are made with FGI.

3. **Seed Cleaning**. The Grower shall harvest seed into FGI's specifically designated and uniquely colored Roundup Ready alfalfa seed bins and Grower will secure bins and seed as prescribed by FGI. The Grower shall be solely responsible for all costs and expenses related to seed cleaning at company's published rates. Cleaning fees will be deducted from each year's seed services payment.

4. **Delivery**. The Grower agrees to ship all of the proprietary seed produced to FGI promptly as requested by FGI and in accordance to terms of this agreement. Freight to be paid as follows: grower to pay for the dirt portion and FGI to pay for clean portion of the seed.

5. **Quality Standards**. Seed specifications shall be as follows:
   a. 99.90% or better purity *
   b. 90% or better germination, including hard seed *
   c. Roundup Ready trait purity equal to or greater than 90% **
   d. free of noxious weeds as defined by federal and state regulations *
   e. less than .05% crop seeds *
   f. less than .02% weed seeds *
   g. * Analyses to be completed by or audited by an official seed testing technologist.
   h. ** Any analyses to be completed by or audited by a Monsanto Roundup Ready trait-licensed facility.
6. **Payment**. Contract service fee will be calculated per pound of clean seed produced after adjustments for seed quality. FGI agrees to pay the Grower for services as described herein:

   2007: $_____ 2008: $_____ 2009: $_____

   a. 50% payment will be made upon estimation of clean seed multiplied by the price per pound stated above no later than December 1 of the applicable crop year; balance will be paid no later than March 1 of the applicable crop year.
   b. During the final year of the contract, FGI shall retain 50% of the final payment until firm arrangements have been made to destroy field(s) after seed harvest and prior to first flower in the subsequent year.
7. **Service Specifications**. The Grower hereby grants FGI or FGI designees the right to enter upon the

acreage described above for the inspection of the crop described above and to determine if the Grower is in compliance with the terms and conditions of this Agreement. FGI may make suggestions for the betterment of the crop. FGI shall not be liable for any damages that may result from its presence on such acreage or its suggestions.

a. *Seed Production Husbandry.* Grower shall produce seed in accordance with federal, state and local regulations and shall adhere to FGI Best Practices and FGI Seed Grower Training for Roundup Ready Alfalfa Seed Production. Grower acknowledges receipt of the FGI Best Practices and FGI Seed Grower Training for Roundup Ready Alfalfa Seed Production and such documents are specifically incorporated into this Agreement by reference. Grower assumes all liability for and shall indemnify and hold FGI and Monsanto Company harmless from any claims, loss or damage of any kind arising out of or related to Grower's negligence and/or Grower's failure to adhere to federal, state and local regulations, FGI Best Practices and FGI Seed Grower Training for Roundup Ready Alfalfa Seed Production.

b. *Glyphosate formulations, rates and timings allowed*: Roundup Ready trait performance may be affected by glyphosate herbicide product formulation, rate and timing. Grower agrees to use only those glyphosate products that are officially labeled for use in Roundup Ready alfalfa seed production. Further, grower agrees to adhere to the maximum Roundup herbicide

application rates and timings specified in the FGI Best Practices which Grower acknowledges may be different from, specifically, less than, those rates and timings allowed by the Roundup herbicide label.

c. *Equipment cleaning*: To facilitate the production of high quality seed Grower agrees that all equipment used by Grower in the field(s) will be well-cleaned when it is moved between different varieties or species of seed crops.

8. **Relationship of the Parties**. It is mutually understood and agreed by the parties that Grower is an independent contractor performing services for FGI. All debts, obligations, and liabilities incurred by the Grower in the performance of this Agreement shall be the sole responsibility of the Grower. Under no circumstances shall FGI be liable or responsible for any claim for damages or compensation which may result from the use of supplies, pesticides, materials, or equipment in or from any other matter relating to the performance of this Agreement; including but not limited to any landlord's claim. Nothing herein shall be construed to constitute the Grower as an agent or employee of FGI or FGI as an agent or employee of the Grower.

9. **Acknowledgement of Third Party Interest**. Grower acknowledges and agrees that Monsanto Company is a third party beneficiary of and under this Agreement, is the owner of certain patent rights relevant to the Roundup Ready alfalfa and co-owner of the events, and therefore has certain rights and benefits under this Agreement including, without limitation, full rights to enforce any

obligations of Grower under this Agreement and/or seek any available remedy for any breach of this Agreement by Grower or any other act or omission by Grower as if Monsanto Company was a signatory hereto. (Roundup Ready® is a Monsanto patent protected trait and trademark.).

10. Service Fee. The Grower expressly represents that he is unrestricted by law or lien, lease, or similar contract from agreeing directly with FGI as to the fee to be paid by FGI to the Grower for the services described herein. The service fee shall constitute full compensation to the Grower for the Grower's services. In the event that the Grower breaches his contractual obligations or violates other covenants, warranties, or agreements contained herein, FGI may direct and the Grower agrees to carry out the direction that the Grower shall terminate the alfalfa acreage described above and destroy any of the future crop of seed described in this Agreement. The parties agree that this shall be the Grower's sole right to compensation under this Agreement or to satisfy any obligations imposed by law. FGI agrees to pay the Grower on a simple fee for services rendered basis as compensation for the Grower's services for the crop, provided that the services meet the certified and trait quality standards set forth above; the service fee is based on the quality and quantity of seed produced by the Grower. The parties agree that the fee which FGI is willing to pay the Grower for the Grower's services shall be lower if the seed produced by the Grower does not meet the seed quality standards set forth above or if Grower fails to satisfactorily perform his obligations.

11. **Seed Quality**. *Germination*: If for any reason all or part of said crop fails to meet the agreed percent minimum germination, Company shall compensate Grower according to the following formula for lots where % germination is higher than 80%, but less than 90% including hard seed. Formula is equal to actual germination multiplied by actual pounds divided by 90% to arrive at adjusted poundage, which poundage would then become that basis for settlement under this agreement. For seed lots where germination is ≤80%, formula is equal to the actual percentage germination multiplied by $0.01/lb.
12. **Trait Purity**. In the event that a portion or all of a Grower's seed production does not meet the trait purity percentage mentioned above the following will result.
    a. If it is proven that substandard % Trait Purity is the fault of the stock seed (i.e., the stock seed provided to the Grower was less than 90% Roundup Ready), Grower will be paid without deductions.
    b. Alternatively, if it is proven that the stock seed was as represented (=90% Trait Purity) Grower will assume the responsibility for loss of trait purity on the affected portion or lot of seed. As is the case for all varieties of seeds, substandard purity will result from accidental, intentional, negligent or inappropriate seed handling procedures (e.g., stock seed planting error, failure to adequately clean-out combines, seed mixing during harvest, etc.). In this case, FGI and Grower will attempt to negotiate a new,

lower per pound service payment on the substandard seed portion. FGI will not guarantee any payment price for severely affected seed lots. Grower is advised that he may not sell or use the substandard Roundup Ready seed or use any seed in a manner that conflicts with the Monsanto Technology Use agreement.

13. **Confidentiality**. Terms and conditions of this agreement are FGI confidential business information and may not be disclosed to third parties without the prior written authorization of FGI.

14. **Assignment**. The services to be performed by the Grower are personal in nature and, therefore, this Agreement and the Grower's rights and obligations hereunder may not be assigned or otherwise transferred by the Grower. Any attempt by Grower to assign or otherwise transfer his rights or obligations shall be void.

15. **Severability**. In the event one or more provisions of this Agreement should be or become illegal, invalid, or unenforceable, then the parties will substitute legal, valid and enforceable provisions for such illegal, invalid ones. The substituted provisions shall be drafted so that in their economic impact they closely resemble the illegal, invalid or unenforceable provisions that it can be reasonably assumed that the parties would have contracted on the basis of those new provisions.

16. **Injunctive Relief**. It is recognized and agreed to by the parties hereto that irreparable damage would result from any breach of this Agreement.

Each party agrees that a party injured by a breach or a threatened breach of this Agreement shall have the remedy of a restraining order or other appropriate equitable relief to enforce this Agreement in addition to all other remedies approved by law.

17. **Liens**. The Grower warrants that he has the undisputed right to contract to provide seed production services on the above-described land. The Grower represents and warrants that all seed produced for FGI by the Grower hereunder shall be free from all liens, claims, and encumbrances including, but not limited to any other statutory or common law liens. Stand take-out expenses are the sole responsibility of the Grower.

18. **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the state of Minnesota.

19. **Entire Agreement**. This Agreement sets forth the entire agreement between Grower and FGI with respect to the transactions contemplated hereby or related thereto, superseding in all respects any and all prior oral or written agreements or understandings relating thereto. This Agreement shall be amended or modified only by a written instrument signed by both Grower and FGI.

IN WITNESS WHEREOF, authorized representatives of the parties hereto have executed this Agreement the day and year first above written.

Grower	FORAGE GENETICS, INC.
By: _____ (signature)	By: _____ (signature)
_____ (printed name)	By: Jose Arias
Title: _____	Title Director of Seed Production
Company: _____	Company: Forage Genetics Inc.
Address: _____ _____	Address: P.O. Box 339 Nampa, ID 83653

[Logo omitted]
Forage
Genetics
International

FGI CONFIDENTIAL

FGI Best Practices & Seed Grower Training for Roundup Ready Alfalfa Seed Production

1. **Objectives and Overview**
   a. Training Objective: Grower understands the expectations and requirements of the Roundup Ready alfalfa technology, and proper stewardship of the RR trait.
   b. RRA Grower training is a requirement of FGI's seed production policy
   c. Use of Roundup herbicide in RRA seed production will be discussed
   d. Roundup Ready alfalfa varieties are patent-protected and Internationally regulated
      i. RRA is approved for commercial seed production in the U.S. (only)
      ii. Certain key alfalfa importing countries have also approved RRA hay import, but the U.S. is the only country where licensed seed or hay production can occur at the present time.
      iii. All RRA seed fields must be specifically grown under a Monsanto trait license ; all RRA hay fields must also be grown under a Monsanto trait license
   e. FGI is available to answer Grower's concerns and challenges
      *i. *Grower's signature at the conclusion of this training indicates that RRA Best Practices*

Seed Grower Training has been successfully completed.

2. **Roundup Ready Trait Stewardship in Seed Production**
   a. FGI has instituted voluntary commercial seed production policies = industry norms
   b. Roundup Ready seed production is modeled on *Foundation Class* seed production practice
   c. All RRA seed growers must agree to follow the FG RRA seed production policies as described in this training and as required by production contracts

3. **Required Monsanto License**
   a. Seed growers must have signed the Monsanto Technology/Stewardship Agreement (MTA) which is a limited use license to use all Monsanto traits. One Monsanto license number covers all subsequent RRA production fields for the Grower and renews automatically each year. The grower's license must be provided to FGI prior to stock seed delivery.

4. **Grower's Responsibilities Include:**
   a. Full confidentiality of FG contract terms, FG Best Practices, field location and variety name & type
   b. Monsanto Technology / Stewardwship Agreement (MTA): Grower must read and follow MTA trait license obligations.

c. Observe patent rights: All RRA stock seed and harvested seed contains patent-protected, Roundup Ready® trait, therefore:
   i. All seed transfer/sale is exclusive between Grower and FGI; no seed may be sold by Grower to other parties
   ii. Grower may not save seed for any purpose as per MTA

d. Observe all federal, state and local regulations:
   i. It is the Grower's responsibility to know and obey current federal, state and local regulations affecting their agricultural practices. *Some Examples are as follows:*
   ii. Federal Laws and Regulations
      1. Pesticide use labels and restrictions
      2. U.S. Patent Rights for RR technology
      3. Plant Variety Protection; Federal Seed Act
      4. Import or export of pollinators (Plant Protection and Quarantine)
   iii. State Laws and Regulations
      1. Noxious or prohibited weeds, pathogens or insects
      2. Pesticide label registrations or restrictions
   iv. Local Laws and Regulations
      1. Pesticide use notifications: field posting
      2. Possible ban/restrict biotechnology use.

e. Bees: Manage pollinators to minimize pollen flow to conventional/other variety fields

i. No bee domicile movement from RRA to conventional alfalfa seed fields until pollination is finished for the year.
   1. Once fees are in RRA seed fields, they may only be moved among RRA fields. It is the Grower's responsibility to inform their pollinator contractors or bee keepers of this requirement.

ii. Grower to locate domiciles to maximize domicile distance to other varieties, as reasonable and appropriate to each field.

iii. The main pollinator bee species will be stated on each FGI Seed Grower Contract. FGI uses voluntary isolation policies that are specific to the main pollinator species.

f. Isolation: Grower will assist FGI with field location planning and isolation zone monitoring; facilitate crop improvement inspections as requested.

   i. The FGI voluntary pollinator species-specifc isolation policy is as follows (distance to conventional seed at planting of RRA): Leafcutter bee = 900 ft*; Alkali bee = 1 mile; and, Honeybee = 3 miles.

   ii. *Specifically, fields eligible for RRA seed production using leafcutter bees are = 900 feet from any preexisting conventional alfalfa that will be grown for seed. (Note: 900 ft is the AOSCA Foundation Class requirement.) Ideally, =900 ft isolation would be maintained throughout the life of the RRA stand; however, it is not a FGI Grower responsibility or a FGI policy requirement to

maintain 900 ft, indefinitely. Likewise, different distances are required using other main pollinators.

iii. Once the RRA field is planted, FGI will quickly report its location and planting date to the local seed certifying organization. Biotech-sensitive alfalfa seed producers can then use this third party service to assist them in planning their field locations to meet their company's isolation or field crop history goals.

iv. If the RRA Grower learns that new alfalfa seed field(s) are planned or planted in close proximity the RRA field, Grower is asked to communicate this information to FGI. Management strategies for maintaining RRA seed quality (varietal/trait purity) may be implemented by FGI using this information.

g. Trait Purity: RRA stock seed is guaranteed by FG to have =90% RR plants; up to 10% non-RR plants or "nulls" are normal and expected.

i. Grower must apply sufficient Roundup herbicide to kill the <10% nulls prior to 9 inches of growth.

ii. Apply only labeled Roundup® brand herbicides to the field

iii. *Minimum requirement* for Roundup herbicide is 1 application per year applied prior to 9 inch height of stems

h. Weeds and In-Crop Volunteers: Manage weeds and volunteers using integrated weed control strategies (e.g., Grower's conventional practices supplemented with Roundup herbicide)

i. Minimizes risk of weed shifts or development of tolerant weeds

ii. Maintains variety: RRA seed fields need non-Roundup practices to control in crop volunteers in carry-over fields

iii. Glyphosate Use Policy for RRA Seed Fields
Glyphosate timing allowed by FGI Best Practices Policy is different from, specifically, *less than*, those timings allowed by the Roundup herbicide label for seed production. Roundup applied anytime during flower (early bud to ripe pod) may reduce seed yield and cautionary text is on the Roundup® herbicide seed production labels.

1. FORMULATIONS: Grower will only use those glyphosate products that are officially labeled for use in Roundup Ready Alfalfa seed production. Labeled formulations for seed production are listed on page 6.
2. TIMING: **To assure optimum clean seed yield, FG requires Grower to apply Roundup when alfalfa is less than 9 inches tall and at least 3 weeks before true bud formation.** Grower must not use Roundup within 3 weeks of true bud stage. FG strongly recommends that Grower should use other weed control methods prior to or during bloom period. See page 6.
3. RATE: Grower will not exceed the single application use labeled rate.

i. Stand Take-Out:

i. Field must be destroyed at the expiration/termination of the seed contract. Take-out must be completed prior to first flower in the subsequent year so that seed certification services can verify stand termination.

ii. Stand termination and volunteer management measures must be sufficient to allow seed certification inspectors to validate stand take-out and to render the alfalfa stand worthless for any unlicensed purpose or use (e.g., unlicensed seed, forage, hay or pasture).

iii. RRA stand take-out **date** and **method** must be reported to FGI and stand destruction verified by local crop improvement (use RRA Stand Take Out form, page 8).

iv. Plan to use a subsequent crop that allows Grower management of RRA alfalfa volunteers should they occur.

j. Sanitation requirements: Management equipment to minimize seed mixture potential *Examples:*

i. Planter inspection, clean-down before and after use

ii. Combine inspection, clean-down thoroughly before and after use

iii. Remove alfalfa stems / leaves from equipment

iv. RRA seed bins may only be used for RRA seed; maintain physical separation of varieties in storage; inspect bins before use

v. Handle all like-trait varieties together; plan for harvest sequence of fields to maintain best separation of varieties by trait type.

vi. Clean all seed handling equipment to avoid mixing biotech and conventional seed

vii. Return unused, unopened stock seed to FGI for credit; maintain in clean storage areas

k. COMMUNICATION: Immediately communicate questions or concerns to FGI field managers

l. Field records: FGI Required Information

i. Planting date; actual acres planted; seed rate/acre; stock seed received/returned

ii. Accurate field address with latitude/longitude (decimal degrees) and local field map

iii. Roundup herbicide application date(s), rate(s), formulation used and alfalfa growth stage at application must be reported to FG within one week of application

iv. Seed box/bin numbers used for harvest

v. Stand destruction date and methods used (use Stand Take Out Form)

5. FGI (Production / Staff) Responsibilities Include:

a. Field production personnel will work in close partnership with Grower

b. Must comply with FGI's voluntary, but binding agreements with local crop improvement organizations:

i. FGI will report each field location, planting date and stand take-out date to local crop improvement organizations

c. RRA Stock seed to be coated purple for easy Grower identification

d. Annual communication of changes to FG Best Practices, should they occur

6. **Grower Questions or Additional Discussion Time**

7. **Supplemental information for review:** 1) current MTA, and, 2) Roundup labels for RRA seed

8. **FGI Key Communications to Growers (pages 5-6)**

9. **Stand Take Out Verification Form (page 7)**

10. **Signature page for Grower Records (page 8)**

11. **Signature page for FGI Records (page 9)**

[Logo omitted]

Forage
Genetics
International

FGI CONFIDENTIAL

FGI Key Communications to RR Alfalfa Seed Growers

Confidential: Policies and grower recommendations are FGI confidential business information and may not be disclosed to third parties without the prior written authorization of FGI.

ROUNDUP READY TRAIT PURITY (% RR)	
STOCK SEED **=90%**	FGI will provide Grower with stock seed that is =90% Roundup Ready. Roundup Ready is a genetic trait that is stable from one seed generation to the next, just like pest resistance or flower color traits. **NOTE: Due to the genetic diversity of alfalfa, up to 10% of seedlings are susceptible and will not survive the first application of Roundup herbicide.** The initial application is necessary to eliminate the effects of stand gaps created by loss of non Roundup Ready plants and to ensure adequate spray coverage of emerging weeds before crop canopy interference. Removal of Roundup susceptible seedlings prior to bud is required to enable high %RR in grower-delivered seed

	(see Roundup Application Rates and Timings below).
GROWER-DELIVERED SEED =90%	Contracts require that Grower deliver seed to FGI that is =90% Roundup Ready (refer to Contract for details). Observe Roundup application requirements to optimize %RR. **MONSANTO LICENSE REQUIREMENT:** All RR seed is patent protected. All seed produced from the above acreage is property of FGI and Grower must deliver all seed to FGI. No "common seed", saved seed, variety not stated (VNS) or sprout channel seed transfers are allowed (see Monsanto Technology/Stewardship Agreement, etc.).

Pollinator Movement Policy
Once bees are put into a Roundup Ready seed field, Grower may not relocate or allow others to move the bees or their domiciles to any conventional alfalfa seed field until after pupation has occurred.

Observe Best Practice for Equipment & Handling
Seed quality is negatively affected by seed mixing, dirt, debris, incorrect equipment adjustment and errors.
Grower must take all precautions needed to ensure that %RR, germination and varietal purity are optimized. Planters, cultivators, spray rigs, swathers

and combines must be cleaned <u>before</u> and <u>after</u> use in RR fields.

Stand Take-out Requirement
Roundup Ready alfalfa seed stands MUST be killed at end of contract term; volunteers must be controlled. Stands must be killed after seed harvest and prior to first flower the following season. Leasers must work with landlords to assure stand take-out and successful volunteer control. Report stand take-out to FGI.

<u>FGI'S ROUNDUP HERBICIDE CONTRACT REQUIREMENTS, RECOMMENDATIONS AND PROHIBITIONS FOR SEED GROWERS: HIGHLIGHTS</u>	
RR trait performance may be affected by glyphosate herbicide product formulation, rate and timing. FGI's Roundup application requirements and recommendations are supplemental to the Roundup labels for RRA seed production. Recommendations are based on FGI experience and are provided to Grower to optimize seed quantity and quality. Grower assumes all responsibility for pesticide applications.	
FG POLICY:	**Roundup** <u>must</u> <u>not</u> be applied between 9 inches growth (prebud) and seed harvest. Grower must report Roundup herbicide usage history to FGI.
<u>ROUNDUP FORMULATIONS</u>	At the present time, ***<u>only</u>*** Roundup UltraMAX II®, WeatherMAX® and or

Roundup UltraMAX II® WeatherMAX® OriginalMAX®	OrginalMAX® are labeled to be used for RRA seed production*. *Formulation label approvals vary by state; RRA seed production is not a registered use in all states. No other glyphosate-containing products may be applied during the life of the stand; use of non-labeled products is a clear violation of State and Federal Laws. FGI recommends that Grower makes advance arrangements for timely delivery of Roundup herbicide.
ROUNDUP TIMING and RATES	**Rates given are for UltraMAX II® (UMII), WeatherMAX® (WM) and OriginalMAX® (OM) only.** Use sufficient labeled herbicides and mechanical controls for a clean start each season. Control in-crop volunteers and weeds using an integrated control approach. In-crop volunteers will not be controlled by Roundup. **Roundup *must not* be applied between 9 inches growth and harvest.**

3-4 Trifoliolate	**3-4 Trifoliolate Stage*** **Roundup UMII, WM or OM: 32 to 44 oz/ac** * FG RRA Variety Required Treatment: Most susceptible plants will be killed. FOR EACH ROUNDUP APPLICATION GROWER MUST RECORD APPLICATION RATE / DATE / STAGE OF GROWTH AND REPORT TO FGI WITHIN 1 WEEK OF APPLICATION.
Vegetative (<9 inch height) **After Mid Vegetative**	**Early to Mid Vegetative Stage Roundup** **UMII, WM or OM: 32 to 44 oz/ac** Apply Roundup at rate needed to control weeds and/or kill Roundup susceptible escapes. FOR EACH ROUNDUP APPLICATION GROWER MUST RECORD APPLICATION RATE / DATE / STAGE OF GROWTH AND REPORT TO FGI WITHIN 1 WEEK OF APPLICATION. Grower is strongly encouraged to use mechanical or soil residual (non-glyphosate) herbicides to address mid to late-season weed problems and/or control in-crop volunteers.

Do not apply Roundup	**Mid Vegetative Stage to Seed Harvest** **Roundup Rate: FG prohibited** FG prohibits Grower from using Roundup after 9 inch crop height. Crop injury (reduced seed yield) can occur; see label precaution. **Apply non-glyphosate herbicide with soil residual for weed control.**

VERIFICATION OF STAND TAKE-OUT TO TERMINATE THE PRODUCTION OF ROUNDUP READY® ALFALFA SEED

The AGREEMENT: The Grower planted the FGI Proprietary stock seed described below on the acreage described below. In accordance with the terms of the Proprietary Seed Services Agreement for the Production of Roundup Ready Alfalfa Seed, upon expiration or termination of the agreement, the grower must take such actions as are necessary to prevent any future seed harvest or unlicensed use for hay, forage or grazing. Stand destruction must occur not later than first flower in subsequent year. Grower must notify FGI of each stand take-out date and method used to destroy the stand. FGI must perform on-site verification that each field has been killed and FGI will notify local crop improvement organization of stand termination.

Use a separate form for each field or field group reported to crop improvement.

	Experimental or Variety Name:					
#	**Field names**	**Number of Acres**	**Field Location: Town-Range-Section & County**	**Latitude / Longitude (original GPS Coordinate)**	**# ACRES + DATE(s) + METHOD (s)**	**SITE VISIT VERIFICATION DATE(s)***
1						

	Experimental or Variety Name:					
#	Field names	Number of Acres	Field Location: Town-Range-Section & County	Latitude / Longitude (original GPS Coordinate)	# ACRES + DATE(s) + METHOD (s)	SITE VISIT VERIFICATION DATE(s)*
2						
3						
Total no. acres this contract planted:				Total no. acres reported to be killed:		
FGI representative verifying Information Signature(s) Date(s)				FGI representative notifying crop improvement Signature(s) Date(s)		

GROWER

By: _____ (signature)

By: _____(printed name)

Title: _____

Company: _____

Address: _____

_____

FORAGE GENETICS INTERNATIONAL

By: _____ (signature)

By: _____

Title: _____

Company: Forage Genetics International

Address: P.O. Box 339, Nampa, ID 83653

Facsimile:(208)466-3684 Telephone:(208)466-3568

These signatures confirm that the Grower has received the FGI Best Practices for Roundup Ready® Alfalfa Seed Production

FGI has communicated FGI Best Practices to the Grower prior to initial RRA seed field planting and will update grower annually, thereafter.

FG Staff Conducting Initial Grower Training:

PRINT NAME AND ADDRESS	SIGNATURE AND DATE
FG Representative: Forage Genetics P.O. Box 339 Nampa, ID 83653 Telephone: (208) 466-3568	_____ _____

Grower Acknowledgement of Training and or Receipt of FGI Best Practices:

PRINT NAME AND ADDRESS	SIGNATURE AND DATE
Telephone number: _____	_____ _____

GROWER TO RETAIN THIS PAGE WITH BEST PRACTICES

Page 9 signature page will be detached for
FGI OFFICE
Grower must retain pages 1 through 8 of
Best Practices

These signatures confirm that the Grower has received the FGI Best Practices for Roundup Ready® Alfalfa Seed Production

FGI has communicated FGI Best Practices to the Grower prior to initial RRA seed field planting and will update grower annually, thereafter.

FG Staff Conducting Initial Grower Training:

PRINT NAME AND ADDRESS	SIGNATURE AND DATE
FG Representative: Forage Genetics P.O. Box 339 Nampa, ID 83653 Telephone: (208) 466-3568	_____ _____

Grower Acknowledgement of Training and or Receipt of FGI Best Practices:

PRINT NAME AND ADDRESS	SIGNATURE AND DATE
Telephone number: _____	_____ _____

FGI OFFICE COPY
TO BE DETACHED FROM GROWER'S PACKET

2007 MONSANTO TECHNOLOGY / STEWARDSHIP AGREEMENT
(*Limited Use License*)

PLEASE MAIL THE SIGNED 2007 MONSANTO TECHNOLOGY / STEWARDSHIP AGREEMENT TO:
Grower Licensing, Monsanto,
622 Emerson Road, Suite 150,
St. Louis, MO 63142

GROWER INFORMATION (please print)

Please complete this section with your business information. To sign this Agreement you must be the operator/grower for all fields that will grow plants from Seed you obtain containing Monsanto Technologies (defined below). You represent that you have full authority to and do hereby bind to this Agreement yourself, all entities for which you obtain Seed, all individuals and entities having an ownership interest in any entities for which you obtain Seed, and that Monsanto Company has not barred any of those individuals or entities from obtaining this limited-use license. Your name must be filled in and must match the signature below. This Monsanto Technology/Stewardship Agreement becomes effective if and when Monsanto issues the Grower a license number from Monsanto's home office in St. Louis, Missouri. Monsanto does not authorize seed dealers or seed retailers to issue a license of any kind for Monsanto Technologies.

* * *

THIS SPACE FOR MONSANTO OFFICE USE ONLY, PLEASE LEAVE THIS SECTION BLANK:

Lic. #: Batch #: Date:

This Monsanto Technology/Stewardship Agreement Is entered into between you (Grower) and Monsanto Company (Monsanto) and consists of the terms on this page and on the second page.

This Monsanto Technology/Stewardship Agreement grants Grower a limited license to use Roundup Ready® Soybeans, YieldGard® Corn Borer corn, YieldGard® Rootworm corn, YieldGard® Rootworm with Roundup Ready® Corn 2, YieldGard® Plus corn, YieldGard® Plus with Roundup Ready Corn 2, Roundup Ready Corn a, YieldGard® Corn Borer with Roundup Ready® Corn 2, Roundup Ready cotton, Bollgard® cotton, Bollgard® with Roundup Ready® cotton, Bollgard II® cotton, Bollgard II® with Roundup Ready® cotton, Roundup Ready® Flex cotton, Bollgard II® with Roundup Ready® Flex cotton, Bollgard® with Roundup Ready® Flex cotton, Mavera® High Value Corn with Lysine, Vistive™ Soybeans, Roundup Ready® Sugarbeets, Roundup Ready® Canola, and Roundup Ready® Alfalfa (Monsanto Technologies). This Agreement also contains Grower's stewardship responsibilities and requirements associated with the Monsanto Technologies.

GENERAL TERMS:

Grower's rights may not be transferred to anyone else without the written consent of Monsanto. If Grower's

rights are transferred with Monsanto's consent or by operation of law, this Agreement is binding on the person or entity receiving the transferred rights. If any provision of this Agreement is determined to be void or unenforceable, the remaining provisions shall remain in full force and effect.

Grower acknowledges that Grower has received a copy of Monsanto's Technology Use Guide (TUG). To obtain additional copies of the TUG, contact Monsanto at 1-800-768-6387 or go to www.Farmsource.com. Once effective, this agreement will remain in effect until either Grower or Monsanto choose to terminate the Agreement. Information regarding new and existing Monsanto Technologies, including any additions or deletions to the U.S. patents licensed under this agreement, and any new terms will be mailed to you each year. Continuing use of Monsanto Technologies after receipt of any new terms constitutes Grower's agreement to be bound by the new terms. If any provision of this Agreement is determined to be void or unenforceable, the remaining provisions shall remain in full force and effect.

GROWER RECEIVES FROM MONSANTO COMPANY:

- A limited use license to purchase and plant seed containing Monsanto Technologies ('Seed") and apply Roundup agricultural herbicides and other authorized non-selective herbicides over the top of Roundup Ready crops. Monsanto retains ownership of the Monsanto Technologies including the genes (for example, the Roundup Ready gene) and the gene technologies. Grower receives the right to use the Monsanto Technologies subject to the conditions

specified in this Agreement and for spring canola in a separate use agreement.

- Monsanto Technologies are protected under U.S. patent law. Monsanto licenses the Grower, under applicable patents owned or licensed by Monsanto, to use Monsanto Technologies subject to the conditions listed in this Agreement. This license does not authorize Grower to plant Seed in the United States that has been purchased in another country or plant Seed in another country that has been purchased in the United States. Grower is not authorized to transfer Seed to anyone outside of the U.S.
- Enrollment for participation in Roundup Rewards' program.
- A limited use license to prepare and apply on glyphosate-tolerant soybean, cotton, alfalfa, or canola crops (or have others prepare and apply) tank mixes of, or sequentially apply (or have others sequentially apply), Roundup agricultural herbicides or other glyphosate herbicides labeled for use on those crops with quizalofop, clethodim, sethoxydim, fluazifop, and/or fenoxaprop to control volunteer Roundup Ready Corn 2 in Grower's crops for the 2007 growing season. However, neither Grower nor a third party may utilize any type of co-pack or premix of glyphosate plus one or more of the above-identified active ingredients in the preparation of a tank mix.

PLEASE MAIL THE SIGNED 2007 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT TO: Grower Licensing, Monsanto, 622 Emerson Road, Suite 150, St. Louis, MO 63141. This Monsanto

Technology/Stewardship Agreement becomes effective if and when Monsanto issues the Grower a license number from Monsanto's home office in St. Louis, Missouri. Monsanto does not authorize seed dealers or seed retailers to issue a license of any kind for Monsanto Technologies.

UNITED STATES PATENTS:

The licensed U.S. patents include: for YieldGard® Corn Borer corn - 5,484,956; 5,352,605; 5,424,412, 5,859,347; 5,593,874; 6,180,774; 6,331,665; for YieldGard® Corn Rootworm corn - 5,110,732; 6,174,724; 5,484,956; 5,352,605; 5,023,179; 6,063,597; 6,331,665; 6,501,009; for YieldGard® Plus corn - 5,023,179; 5,352,605; 5,484,956; 5,424,412; 5,859,347; 5,593,874; 6,063,597; 6,174,724; 6,331,665; for Roundup Ready® Corn 2 - 4,940,835; 5,188,642; 5,359,142; 5,196,525; 5,322,938; 5,164,316; 5,352,605; 5,554,798; 5,593,874; 5,859,347; 5,424,412; 5,633,435; 5,804,425; 5,641,876; 6,825,400; 5,717,084; 5,728,925; 6,083,878; 6,025,545; for Roundup Ready® corn - 4,940,835; 5,188,642; 6,025,545; 5,554,798; 6,040,497; 5,641,876; 5,717,084; 5,728,925; 6,083,878; for YieldGard® Corn Borer with Roundup Ready® Corn - 5,484,956; 5,352,605; 5,424,412; 5,859,347; 5,593,874; 6,331,665; 4,940,835; 5,188,642; 5,359,142; 5,196,525; 5,322,938; 5,164,316; 5,554,798; 5,633,435; 5,804,425; 5,641,876; 5,717,084; 5,728,925; 6,083,878; 6,025,545; for Roundup Ready® Soybeans - 4,940,835; 5,188,642; 5,352,605; 5,633,435; 5,530,196; 5,717,084; 5,728,925; 5,804,425; for Roundup Ready® cotton - 5,633,435; 5,352,605; 5,530,196; 5,188,642; 4,940,835; 5,804,425; 6,051,753; 6,018,100; 5,378,619; 6,174,724; 5,159,135; 5,004,863; 5,728,925; 5,717,084; 6,083,878; 6,753,463; for Bollgard® cotton - 5,359,142;

5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,164,316; 6,174,724; 5,880,275; 5,159,135; 5,004,863; 6,943,282; for Bollgard® with Roundup Ready® cotton - 5,633,435; 5,359,142; 5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,188,642; 5,164,316; 4,940,835; 5,717,084; 5,728,925; 6,051,753; 6,018,100; 5,378,619; 6,174,724; 5,159,135; 5,004,863; 6,083,878; 5,880,275 5,804,425; 6,943,282; 6,753,463; for Bollgard II® cotton - 6,489,542; 5,359,142; 5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,164,316; 6,174,724; 5,880,275; 5,159,135; 5,004,863; 5,728,925; 5,717,084; 5,338,544; 5,659,122; 5,362,865; 6,943,282; for Bollgard II® with Roundup Ready® cotton - 5,633,435; 6,489,542; 5,359,142; 5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,188,642; 5,164,316; 4,940,835; 5,717,084; 5,728,925; 6,051,753; 6,018,100; 5,378,619; 6,174,724; 5,159,135; 5,004,863; 6,083,878; 5,880,275; 5,804,425; 5,338,44; 5,362,865; 5,659,122 6,943,282 6,753,463; for Roundup Ready® Canola - 6,051,753; 6,018,100; 5,378,619; 5,718,925; 5,717,084; 5,804,425; 5,633,435; 5,188,642; 4,940,835; 5,463,175; 6,083,878; 5,750,871; 5,463,174; 5,188,958; RE38825; for Roundup Ready® Sugarbeets - 5,378,619; 5,463,175; 5,633,435; 5,164,316; 5,196,525; 5,322,938; 5,359,142; 5,352,605; 5,530,196; 4,940,835; 5,188,642; 5,717,084; 5,728,925; 6,018,100; 6,051,753; 6,083,878; 5,804,425; 6,174,724; RE38825; for Roundup Ready® Alfalfa - 6,051,753; 6,018,100; 5,378,619; 5,362,865; 5,659,122; 5,717,084; 5,728,925, 5,633,435; 5,804,435; for Roundup Ready® Flex Cotton - 4,940,835; 5,004,863; 5,159,135; 5,188,64;Z; 5,633,435; 5,717,084; 5,728,925; 5,804,425; 6,051,753; 6,083,878; 6,660,911; 6,949,696; 6,753,463; for Bollgard II Roundup Ready® Flex Cotton - 4,940,835; 5,004,863, 5,159,135, 5,188,642; 5,633,435; 5,717,084; 5,728,925; 5,804,425;

6,051,753; 6,083,878; 6,660,911; 6,949,696; 6,753,463; 5,359,142; 5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,164,316; 6,174,724; 5,880,275; 5,959,135; 5,004,863; 6,943,282; for Bollgard II® with Roundup Ready® Flex Cotton - 6,489,542; 5,359,142; 5,352,605; 5,530,196; 5,322,938; 5,196,525; 5,164,316; 6,174,724; 5,880,275; 5,159,135; 5,004,863; 5,728,925; 5,717,084; 5,338,544; 5,659,122; 5,362,865; 4,940,835; 5,004,863; 5,159,135; 5,188,642; 5,633,435; 5,717,084; 5,728,925; 5,804,425; 6,051,753, 6,083,878; 6,660,911; 6,949,696; 6,943,282; 6,753,463; for YieldGard® Plus with Roundup Ready® Corn 2 - 5,023,179; 5,352,605; 5,484,956; 5,424,412; 5,859,347; 5,593,874; 6,063,597; 6,174,724; 6,331,665; 4,940,835; 5,188,642; 5,359,142; 5,196,525; 5,322,938; 5,164,316; 5,352,605; 5,554,798; 5,593,874; 5,859,347; 5,424,412; 5,633,435; 5,804,425; 5,641,876; 6,825,400; 5,717,084; 5,728,925; 6,083,878; 6,025,545; for YieldGard® Corn Borer with Roundup Ready® Corn 2 - 5,484,956; 5,352,605; 5,424,412; 5,859,347; 5,593,874; 6,180,774; 6,331,665; 4,940,835; 5,188,642; 5,359,142; 5,196,525, 5,322,938; 5,164,316; 5,352,605; 5,554,798; 5,593,874; 5,859,347; 5,424,412; 5,633,435; 5,804,425; 5,641,876; 6,825,400; 5,717,084; 5,728,925; 6,083,878; 6,025,545; for YieldGard® Rootworm with Roundup Ready® Corn 2 - 5,110,732; 6,174,724; 5,484,956; 5,352,605; 5,023,179; 6,063,597; 6,331,665; 6,501,009; 4,940,835; 5,188,642; 5,359,142; 5,196,525; 5,322,938; 5,164,316; 5,352,605; 5,554,798; 5,593,874; 5,859,347 5,424,412; 5,633,435; 5,804,425; 5,641,876; 6,825,400; 5,717,084; 5,728,925; 6.083,878; 6,025,545; for MON88017 - 6,063,597; 6,642,030; 5,633,435; 5,804,425; 5,554,798; 5,641,876; 4,940,835; 5,188,642; 5,359,142; 5,196,525; 5,322,938; 5,164,316; 5,858,742; 5,352,605; 5,717,084;

5,728,925; 6,083,878; 6,025,545; for Mavera® high value corn with lysine - 6,329,574; for tank mix 6,239,072

ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Roundup Ready® crops contain genes that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. Roundup agricultural herbicides will kill crops that are not tolerant to glyphosate. Roundup, Roundup Ready, YieldGard, YieldGard Corn Borer and Design. YieldGard Rootworm and Design, YieldGard Plus and Design, Bollgard, Bollgard II, Roundup Technology, Vistive. Roundup Rewards, Grow the Feed, Not the Weeds., and Monsanto Imagine and the Vine Design are trademarks of Monsanto Technology LLC. Mavera is a trademark of Renessen LLC.

* * *

GROWER AGREES:

- To direct grain produced from corn containing trait stacks that include the Roundup Ready Corn 2 and/or YieldGard Rootworm trait(s) to appropriate markets as necessary.
- If growing Roundup Ready Alfalfa to direct any product produced from a Roundup Ready Alfalfa crop or seed, Including hay and hay products, only to those countries where regulatory approvals have been granted, and not to plant Roundup Ready Alfalfa for the production of sprouts. Refer to the Technology Use Guide for additional information.
- To accept and continue the obligations of this Monsanto Technology Stewardship Agreement on any new land purchased or leased by Grower that has Seed planted on it by a previous owner or possessor of the land; and to notify in writing

purchasers or lessees of land owned by Grower that has Seed planted on it that the Monsanto Technology is subject to this Monsanto Technology Stewardship Agreement and they must have or obtain their own Monsanto Technology Stewardship Agreement.

- To implement an Insect Resistance Management program as specified in the applicable Bollgard/Bollgard II cotton and YieldGard corn sections of the most recent Technology Use Guide (TUG) and Insect Resistance Management (IRM) guides and to cooperate and comply with Insect Resistance Management programs.
- To use Seed containing Monsanto Technologies solely for planting a single commercial crop. Not to save any crop produced from Seed for planting and not to supply Seed produced from Seed to anyone for planting other than to a Monsanto licensed seed company.
- Not to transfer any Seed containing patented Monsanto Technologies to any other person or entity for planting.
- To plant Seed for Seed production, if and only if, Grower has entered into a valid, written Seed production agreement with a Seed company that is licensed by Monsanto to produce Seed. Grower must either physically deliver to that licensed Seed company or must sell or use as commodity grain all of the Seed produced pursuant to a Seed production agreement. Grower shall NOT plant any Seed Grower has produced or use or allow others to use Seed containing patented Monsanto Technologies for

crop breeding, research, or generation of herbicide registration data.

- To use on Roundup Ready crops only a labeled Roundup® agricultural herbicide or other authorized non-selective herbicide which could not be used in the absence of the Roundup Ready gene (see TUG for details on authorized non-selective products). Use of any selective herbicide labeled for the same crop without the Roundup Ready gene Is not restricted by this Agreement. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES WHICH ARE LABELED FOR USE IN ROUNDUP READY CROP(S). MONSANTO SPECIFICALLY DISCLAIMS ALL RESPONSIBILITY FOR THE USE OF THESE PRODUCTS IN ROUNDUP READY CROP(S). ALL QUESTIONS AND COMPLAINTS ARISING FROM THE USE OF PRODUCTS MANUFACTURED OR MARKETED BY OTHER COMPANIES SHOULD BE DIRECTED TO THOSE COMPANIES.
- To read and follow the applicable sections of the TUG, which is incorporated into and is a part of this Agreement, for specific requirements relating to the terms of this Agreement, and to abide by and be bound by the terms of the TUG as it may be amended from time to time.
- To acquire Seed containing these Monsanto Technologies only from a seed company with

technology license(s) from Monsanto or from a licensed company's authorized dealer.

- To pay all technology fees due to Monsanto that are a part of, associated with or collected with the Seed purchase price or that are invoiced for the seed.
- Upon written request, to allow Monsanto to review the Farm Service Agency crop reporting information on any land farmed by Grower including Summary Acreage History Report, Form 578 and corresponding aerial photographs, Risk Management Agency claim documentation, and dealer/retailer invoices for seed and chemical transactions.
- To allow Monsanto to examine and copy any records and receipts that could be relevant to Grower's performance of this Agreement.

GROWER UNDERSTANDS:

- Commodity Marketing: Grain/commodities harvested from YieldGard Plus corn, YieldGard Plus with Roundup Ready Corn 2, YieldGard Rootworm with Roundup Ready Corn 2, YieldGard Corn Borer with Roundup Ready Corn 2, and Roundup Ready Canola are approved for U.S. food and feed use but not yet approved In certain export markets where approval is not certain to be received before the end of 2007. As a result, Grower must direct those grain/commodities to the following approved market options: feeding on farm, use in domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only. Go to www.866sellcom.com for a list of Grain Handlers' positions on accepting transgenic corn. The American Seed Trade Association web site

(www.amseed.org) includes a list of grain handlers' positions on accepting transgenic corn. You must complete and send to Monsanto a Market Choices® Grain Marketing Communication Plan. For additional Information on grain market options or to obtain additional forms, call 1-800-768-6387.

- Regulatory approvals: Monsanto Technologies may only be used where the products have been approved for use by all required governmental agencies. For example, some Monsanto Technologies are not approved in all states. Check with your Monsanto representative if you have questions about the approval status in your state.
- Insect Resistance Management (IRM): When planting any YieldGard or Bollgard product, Grower must implement an IRM program including planting a non-*B.t.* refuge according to the size and distance guidelines specified in the Bollgard cotton and YieldGard corn sections of the most recent Monsanto Technology Use Guide Including any supplemental amendments (collectively "TUG") and the crop specific IRM guides. Grower may lose Grower's limited use license to use these products if Grower fails to follow the IRM program required by this Agreement.
- Crop Stewardship & Specialty Crops: Refer to the section on Coexistence and Identity Preservation in the TUG for information on crop stewardship and considerations for production of identity preserved crops.
- Corn Trait Performance: All hybrids containing Monsanto corn traits (YieldGard Corn Borer corn, YieldGard Rootworm corn, YieldGard Plus corn, and

Roundup Ready Corn 2) have been screened for the presence of the appropriate protein and have passed that screening prior to commercial sale. YieldGard Rootworm corn and YieldGard Plus corn hybrids have achieved industry leading success rates in excess of 99%. A small number of these hybrids may infrequently demonstrate variable levels of performance In fields and not meet grower expectations.

MONSANTO'S REMEDIES:

If Grower breaches this Agreement, In addition to Monsanto's other remedies, Grower's limited-use license will terminate immediately. Thereafter, Monsanto will not accept any application for a new Monsanto Technology/Stewardship Agreement unless Monsanto provides in writing an authorization specifically naming Grower. Any such purported agreement that does not contain Monsanto's express authorization (whether a license number has been issued or not) is void. If Grower is found by any court to have breached any term of this Agreement and/or to have infringed one or more of the U.S. patents listed below, Grower agrees that, among other things, Monsanto will be entitled to a permanent Injunction enjoining Grower from making, using, selling, or offering for sale Seed. Additionally, Grower agrees that any such finding of infringement by Grower shall entitle Monsanto to patent infringement damages to the full extent authorized by 35 U.S.C. § 271 et. seq.. Grower will also be liable for all breach of contract damages. If Grower is found by any court to have infringed one or more of the U.S. patents listed below or otherwise to have breached this agreement, Grower agrees to pay Monsanto and the licensed Monsanto

Technology provider(s) their attorneys' fees and costs and other expenses incurred in enforcing rights under the contract including, but not limited to, expenses incurred in the investigation of the breach of this agreement and/or Infringement of one or more of the U.S. patents listed below.

Grower accepts the terms of the following NOTICE REQUIREMENT, LIMITED WARRANTY AND DISCLAIMER OF WARRANTY AND EXCLUSIVE LIMITED REMEDY by signing this Agreement and/or opening a bag of Seed containing Monsanto Technology. If Grower does not agree to be bound by the conditions of purchase or use, Grower agrees to return the unopened bags to Grower's seed dealer.

NOTICE REQUIREMENT:

As a condition precedent to Grower or any other person with an interest in Grower's crop asserting any claim, action, or dispute against Monsanto and/or any seller of Seed containing Monsanto Technologies regarding performance or non-performance of Monsanto Technologies or the Seed in which it is contained, Grower must provide Monsanto a written, prompt, and timely notice (regarding performance or non-performance of the Monsanto Technologies) and to the seller of any Seed (regarding performance or non-performance of the Seed) within sufficient time to allow an in-field inspection of the crop(s) about which any controversy, claim, action, or dispute is being asserted. The notice will be timely only if it is delivered 15 days or less after the Grower first observes the issue(s) regarding performance or non-performance of the Monsanto Technology and/or the Seed in which it is

contained. The notice shall include a statement setting forth the nature of the claim, name of the Monsanto Technology, and Seed hybrid or variety.

LIMITED WARRANTY AND DISCLAIMER OF WARRANTIES:

Monsanto warrants that the Monsanto Technologies licensed hereunder will perform as set forth in the TUG when used in accordance with directions. This warranty applies only to Monsanto Technologies contained in planting Seed that has been purchased from Monsanto and seed companies licensed by Monsanto or the seed company's authorized dealers or distributors. EXCEPT FOR THE EXPRESS WARRANTIES IN THE LIMITED WARRANTY SET FORTH ABOVE, MONSANTO MAKES NO OTHER WARRANTIES OF ANY KIND AND DISCLAIMS ALL OTHER WARRANTIES, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE.

GROWER'S EXCLUSIVE LIMITED REMEDY:

THE EXCLUSIVE REMEDY OF THE GROWER AND THE LIMIT OF THE LIABILITY OF MONSANTO OR ANY SELLER FOR ANY AND ALL LOSSES, INJURY OR DAMAGES RESULTING FROM THE USE OR HANDLING OF SEED CONTAINING MONSANTO TECHNOLOGY (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, PRODUCT LIABILITY, STRICT LIABILITY, TORT, OR OTHERWISE) SHALL BE THE PRICE PAID BY THE GROWER FOR THE QUANTITY OF THE SEED INVOLVED OR, AT

THE ELECTION OF MONSANTO OR THE SEED SELLER, THE REPLACEMENT OF THE SEED. IN NO EVENT SHALL MONSANTO OR ANY SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES.

Thank you for choosing our advanced technologies. We look forward to working with you in the future. If you have any questions regarding the Monsanto Technologies or this license, please call the Monsanto Customer Relations Center at: 1-800-ROUNDUP.

GOVERNING LAW: This Agreement and the parties' relationship shall be governed by the laws of the State of Missouri and the United States (without regard to the choice of law rules).

BINDING ARBITRATION FOR COTTON-RELATED CLAIMS MADE BY GROWER: Any claim or action made or asserted by a cotton Grower (or any other person claiming an Interest in the Grower's cotton crop) against Monsanto or any seller of cotton Seed containing Monsanto Technology arising out of and/or in connection with this Agreement or the sale or performance of the cotton Seed containing Monsanto Technology other than claims arising under the patent laws of the United States must be resolved by binding arbitration. The parties acknowledge that the transaction involves interstate commerce. The parties agree that arbitration shall be conducted pursuant to the provisions of the Federal Arbitration Act, 9 U.S.C. Sec 1 et seq. and administered under the Commercial Dispute Resolution Procedures established by the American Arbitration Association ("AAA"). The term "seller" as used throughout this

Agreement refers to all parties involved in the production, development, distribution, and/or sale of the Seed containing Monsanto Technology. In the event that a claim is not amicably resolved within 3o days of Monsanto's receipt of the Grower's notice required pursuant to this Agreement any party may initiate arbitration. The arbitration shall be heard in the capital city of the state of Grower's residence or in any other place as the parties decide by mutual agreement. When a demand for arbitration is filed by a party, the Grower and Monsanto/sellers shall each immediately pay one half of the AAA filing fee. In addition, Grower and Monsanto/sellers shall each pay one half of AAA's administrative and arbitrator fees as those fees are incurred. The arbitrator(s) shall have the power to apportion the ultimate responsibility for all AAA fees in the final award. The arbitration proceedings and results are to remain confidential and are not to be disclosed without the written agreement of all parties, except to the extent necessary to effectuate the decision or award of the arbitrator(s) or as otherwise required by law.

FORUM SELECTION FOR NON-COTTON-RELATED CLAIMS MADE BY GROWER AND ALL OTHER CLAIMS: THE PARTIES CONSENT TO THE SOLE AND EXCLUSIVE JURISDICTION AND VENUE OF THE U.S. DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION, AND THE CIRCUIT COURT OF THE COUNTY OF ST. LOUIS, MISSOURI, (ANY LAWSUIT MUST BE FILED IN ST. LOUIS, MO) FOR ALL CLAIMS AND DISPUTES ARISING OUT OF OR CONNECTED IN ANY WAY WITH THIS AGREEMENT AND/OR

THE USE OF THE SEED OR THE MONSANTO TECHNOLOGIES, EXCEPT FOR COTTON-RELATED CLAIMS MADE BY GROWER.

THIS AGREEMENT CONTAINS A BINDING ARBITRATION PROVISION FOR COTTON RELATED CLAIMS PURSUANT TO THE PROVISIONS OF THE FEDERAL ARBITRATION ACT, 9 U.S.C. § 1 ET SEQ., WHICH MAY BE ENFORCED BY THE PARTIES.

GROWER SIGNATURE & DATE REQUIRED

_____ _____

Name Date

MONSANTO

2007
TECHNOLOGY USE GUIDE

[Logo omitted]

Introduction

This 2007 Technology Use Guide (TUG) provides a concise source of technical information about Monsanto's current portfolio of technology products and sets forth the requirements and guidelines for the use of these products. As a user of Monsanto Technology it is important that you are familiar with and follow certain management practices. Please read all of the information pertaining to the technology you will be using, including Stewardship and related information.

This technical bulletin is not a pesticide product label. It is intended to provide additional information and to highlight approved uses from the product labeling. Read and follow all precautions and use instructions in the label booklet and separately published supplemental labeling for the Roundup® agricultural herbicide product you are using.

Included in this guide is information on the following:	Pages
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If you have any questions, contact your Authorized Retailer or Monsanto at 1-800-ROUNDUP.

[Graphic omitted]

Stewardship Overview

A Message About Stewardship

Seed and Traits

Monsanto Company is committed to enhancing grower productivity and profitability through the introduction of new modern agricultural biotechnology seed trait technologies (traits). These new technologies bring enhanced value and benefits to growers and growers assume new responsibilities for proper management of those traits. Growers planting seed with biotech traits agree to implement good stewardship practices, including, but not limited to:

- Reading and signing a Monsanto Technology/Stewardship Agreement (MTA) and reading all annual license terms updates before purchase or use of any seed containing a trait. Growers must sign their own Stewardship Agreement.
- Reading and following the directions for use on all product labels and following applicable Stewardship practices as outlined in this TUG.
- Complying with the applicable Insect Resistant Management (IRM) practices for specific biotech traits as mandated by the Environmental Protection Agency (EPA) and set forth in this TUG.
- Utilizing all seed with biotech traits for planting a single crop.

- Selling harvested corn with biotech traits not yet fully approved by the European Union (E.U.) to grain handlers that confirm their acceptance, or using that grain as on-farm feed.
- Not moving material containing biotech traits across boundaries into nations where import is not permitted.

If you have questions about seed stewardship or become aware of individuals utilizing biotech traits in a manner other than as noted above, please call 1-800-768-6387. Letters reporting unacceptable or unauthorized use of biotech traits may be sent to:

Monsanto Trait Stewardship
800 N. Lindbergh Boulevard C3ND
St. Louis, MO 63167.

Provide confidential or anonymous reports as below:

"Anonymous" reporting results when a person reports information to Monsanto in such a way that the identity of the person reporting the information cannot be identified. This kind of reporting includes telephone calls requesting anonymity and unsigned letters.

"Confidential" reporting results when a person reports information to Monsanto in such a way that the reporting person's identity is known to Monsanto. Every effort will be made to protect a person's identity, but it is important to understand that a court may order Monsanto to reveal the identity of people who are "known" to have supplied relevant information.

Technology/Stewardship Agreement

Growers who purchase Monsanto's traited seed for planting are required to execute an MTA and are

instructed to refer to Monsanto's current TUG for information on crop stewardship.

Stewardship Overview

Why is Stewardship Important?

Each component of Stewardship offers benefits to growers:

- Signing an MTA provides growers access to Monsanto's biotech-trait seed technology.
- Following IRM guidelines guards against insect resistance to B.t. technology and therefore enables the long-term viability of this technology.
- Good corn grain and processed products stewardship helps to preserve a continuous open export market for U.S. grain products.
- Proper weed management maintains the long-term effectiveness of glyphosate based weed control solutions.
- Utilizing biotech seed only for planting a single-use crop allows investment for future biotech innovations which will even further improve farming technology.

Practicing these Stewardship activities will enable biotechology's positive agricultural contributions to continue.

Since 1996, Biotech crops have delivered a decade of environmental and economic benefits.

Biotech crops have:

- Been grown by millions of growers on more than one billion acres worldwide.

- Reduced pesticide applications equivalent to a 15 mile-long train of railcars filled with pesticide active ingredient*.
- Been instrumental in the adoption of no-till or reduced tillage practices—saving billions of tons of topsoil, 465 million gallons of diesel fuel, and reducing greenhouse gas emissions equivalent to removing nearly 5 million cars from the road for one year.
- Increased net farm income for U.S. farmers by $10.8 billion through reduced costs and/or higher yields.
- Been included as ingredients in more than one trillion meals.
- Zero scientifically documented, negative health effects.

To learn more, go to: www.biotech-gmo.com.

Together, grower Stewardship practices and Biotechnology benefits enable the sustainability of our land resources, this technology, and farming as a preferred way of life.

*Pesticides registered by the U.S. EPA will not cause unreasonable adverse effects to man or the environment when used in accordance with label directions.

[Graphics omitted]

Insect Resistance Management

An effective IRM program is a vital part of responsible product stewardship for insect-protected biotech products. Monsanto is committed to implementing an effective IRM program for all of its insect-protected B.t. technologies in all countries where they are

commercialized, including promoting grower awareness of these IRM programs. Monsanto works to develop and implement IRM programs that strike a balance between available knowledge and practicality, with grower acceptance and implementation of the plan as critical components.

In the U.S., the EPA requires that Monsanto, and growers who purchase YieldGard® corn and Bollgard®/Bollgard II® cotton products, implement an IRM plan for these insect-protected products. The IRM programs for YieldGard corn and Bollgard/Bollgard II cotton products are based upon an assessment of the biology of the major target pests, realistic consideration of grower needs and practices, and an understanding of appropriate pest management practices. These mandatory regulatory programs have been developed and updated through broad cooperation with grower and consultant organizations, including the National Corn Growers Association and the National Cotton Council, extension specialists, academic scientists, and regulatory agencies.

The IRM programs for YieldGard corn and Bollgard/Bollgard II cotton products contain several important elements. One key component of an IRM plan is a refuge. A refuge is simply a block of the relevant crop (corn for YieldGard and cotton for Bollgard/Bollgard II, respectively) that does not contain a "B.t." technology for the control of the insect pests which are controlled by the planted technology(ies). The lack of exposure to the B.t. proteins means that there will be susceptible insects nearby to mate with any rare resistant insects that may emerge from B.t. products, Susceptibility to the B.t. products is then passed on to their offspring.

preserving the long term effectiveness of the technology. Growers who purchase YieldGard corn and Bollgard/Bollgard II cotton products are required to plant an appropriately designed refuge in association with their fields. How large these refugia need to be, how they should be placed relative to the YieldGard corn and Bollgard/Bollgard II cotton fields, and how they should be managed is described in detail in the sections on those products within this document or the appropriate IRM guide.

Failure to follow IRM guidelines and properly plant a refuge may result in the loss of a grower's access to Monsanto Technologies. Monsanto is committed to the preservation of these technologies. Please do your part to ensure that YieldGard corn and Bollgard/Bollgard II cotton technologies are preserved by implementing an IRM Plan on your farm.

Monitoring Program

Through an agreement with the EPA, Monsanto, or an approved agent of Monsanto, will monitor refuge management practices. The MTA requires that, upon request by Monsanto or its approved agent, a grower is to provide the location of all fields planted with YieldGard, Bollgard and Bollgard II technologies and the locations of all associated refuge areas, to cooperate fully with any field inspections, and allow Monsanto to inspect all YieldGard, Bollgard and Bollgard II fields and refuge areas to ensure an approved insect resistance program has been followed. All inspections will be performed at a reasonable time and arranged in advance with the grower so that the grower can be present if desired.

Weed Resistance Management

Monsanto considers product stewardship to be a fundamental component of customer service and responsible business practices. As leaders in the development and stewardship of Roundup® agricultural herbicides and other products, Monsanto continues to invest significantly in research to understand the proper uses and stewardship of our proprietary herbicide brands. This research, done in conjunction with academic scientists, extension specialists, and crop consultants, includes an evaluation of some of the factors that can contribute to the development of weed resistance and how to properly manage weeds to delay the development of resistance.

Glyphosate is a Group 9 herbicide based on the mode of action classification system of the Weed Science Society of America. Any weed population may contain plants naturally resistant to Group 9 herbicides. The following general recommendations help manage the risk of weed resistance occurring. More specific recommendations are outlined in each Roundup Ready® crop section in this TUG.

Weed Resistance Management Practices:

- Scout your fields before and after herbicide application.
- Start with a clean field, using either a burndown herbicide application or tillage.
    - Control weeds early when they are small.
- Add other herbicides (e.g. a selective and/or a residual herbicide) and cultural practices (e.g. tillage or crop rotation) as part of your Roundup Ready cropping system where appropriate.

- Use the right herbicide product at the right rate and the right time.
- Control weed escapes and prevent weeds from setting seeds.
- Clean equipment before moving from field to field to minimize spread of weed seed.
- Use new commercial seed as free from weed seed as possible.

Monsanto is committed to the proper use and long-term effectiveness of its proprietary herbicide brands through a four-part stewardship program: developing appropriate weed control recommendations, continuing research to refine and update recommendations, education on the importance of good weed management practices, and responding to repeated weed control inquiries through a product performance evaluation program.

Report any incidence of repeated non-performance on a particular weed to the local Monsanto representative, retailer, or county extension agent.

Weed Resistance Management

Control of Glyphosate Resistant Weed Botypes.

Monsanto actively investigates and studies weed control complaints and claims of weed resistance. When glyphosate resistant weed biotypes have been confirmed, Monsanto alerts growers, and develops and provides growers with recommended control measures, which may include additional herbicides or tank mixes or cultural practices. Monsanto actively communicates all of this information to growers through multiple channels, including the herbicide label, supplemental labeling, this TUG, media and written communications,

our website, www.weedresistancemanagement.com, and grower meetings.

Growers must be aware of and proactively manage for glyphosate-resistant weeds in planning their weed control program. When a weed is known to be resistant to glyphosate, then a resistant population of that weed is by definition no longer controlled with labeled rates of glyphosate. Roundup® agricultural herbicide warranties will not cover the failure to control glyphosate resistant weed populations.

* * *

Coexistence and Identity Preserved Production

Coexistence in agricultural production systems and supply chains is not new. Different agricultural systems have co-existed successfully for many years around the world. Standards and best practices were established decades ago and have continually evolved to deliver high purity seed and grain to support production, distribution, and trade of products from different agricultural systems. For example, production of similar commodities such as field corn, sweet corn and popcorn has occurred successfully and in close proximity for many years. Another example is the successful coexistence of oilseed rape varieties with low erucic acid content for food use and high erucic acid content for industrial uses.

The introduction of biotech crops has sparked a debate concerning the coexistence of biotech production systems with conventional cropping systems and organic production. This debate has primarily focused on the potential economic impact of the introduction of biotech products on other systems. The health and safety of biotech products are not an issue because

their food, feed, and environmental safety must be demonstrated before they enter the agricultural production system and supply chain.

The coexistence of conventional, organic, and biotech crops has been the subject of several recent reports. These reports conclude that coexistence among biotech and non-biotech crops is not only possible but is occurring. These reports recommend that coexistence strategies must be developed on a case-by-case basis considering the diversity of products currently in the market and under development, differences in the crops themselves, and variations in regional farming practices and infrastructures. Furthermore, coexistence strategies are driven by market needs and should be developed using current science-based industry standards and management practices. The strategies must be flexible, enabling options for the grower and the food/feed supply chain, and must be capable of being modified as changes in markets and products warrant.

Successful coexistence of all agricultural systems is achievable and depends on cooperation, flexibility, and mutual respect for each system. Agriculture has a history of innovation and change, and growers have always adapted to new approaches or challenges by utilizing appropriate strategies, farm management practices, and new technologies.

The responsibility for implementing practices to satisfy specific marketing standards or certification must lie with that grower who is growing a crop to satisfy a particular market. This is true whether the goal is high-oil corn, white sweet corn, or organically produced yellow corn for animal feed. In each case, the grower is

seeking to produce a crop that is supported by a market price and consequently that grower assumes responsibility for satisfying reasonable market specifications.

Identity Preserved Production

Some growers may choose to preserve the identity of their crops to meet specific markets. Examples of Identity Preservation (I.P.) corn crops include production of seed corn, white, waxy, or sweet corn, specialty oil or protein crops, food grade crops, and any other crop that meets specialty needs, including organic and non-genetically enhanced specifications. Growers of these crops assume the responsibility and receive the benefit for ensuring that their crop meets mutually agreed contract specifications.

Based on historical experience with a broad range of I.P. crops, the industry has developed generally accepted I.P. agricultural practices. These practices are intended to manage I.P. production or quality specifications, and are established for a broad range of I.P. needs. The accepted practice with I.P. crops is that each I.P. grower has responsibility to implement any necessary processes. These processes may include sourcing seed appropriate for I.P. specifications, field management practices such as adequate isolation distances, buffers between crops, border rows, planned differences in maturity between adjacent fields that might cross-pollinate, and harvest and handling practices designed to prevent mixing and to maintain product quality. These extra steps associated with I.P. crop production are generally accompanied by incremental increases in cost of production and consequently of the goods sold.

General Instructions for Management of Pollen Flow and Mechanical Mixing

For all crop hybrids or varieties that they wish to identity, preserve, or otherwise keep separated, growers should take steps to prevent mechanical mixing. Growers should make sure all seed storage areas, transportation vehicles, and planter boxes are cleaned thoroughly both prior to and subsequent to the storage, transportation, or planting of the crop. Growers should also make sure all combines, harvesters and transportation vehicles used at harvest are cleaned thoroughly both prior to and subsequent to their use in connection with the harvest of the grain produced from the crop. Growers should also make sure all harvested grain is stored in clean storage areas where the identity of the grain can be preserved.

Self-pollinated crops, such as soybeans, do not present a risk of mixing by cross-pollination. If the intent is to use or market the product of a self-pollinated crop separately from general commodity use, growers should plant fields at a sufficient distance away from other crops to prevent mechanical mixture.

Growers planting cross pollinated crops, such as corn or alfalfa, who desire to preserve the identity of these crops or to minimize the potential for these crops to outcross with adjacent fields of the same crop kind, should use the same generally accepted practices to manage mixing that are used in any of the currently grown identity preserved crops of similar crop kind.

Growers should take into account the following factors that can affect the occurrence and extent of crosspollination to or from other fields. Information

that is more specific to the crop and region may be available from state extension offices.

- **Cross pollination is limited.** Some plants, such as potatoes, are incapable of cross-pollinating, while others, like alfalfa, require cross-pollination to produce seed. Importantly, cross-pollination only occurs within the same crop kind like corn to corn.
- **The amount of pollen produced within the field can vary.** The pollen produced by the crop within a given field, known as pollen load, is typically high enough to pollinate all of the plants in the field. Therefore, most of the pollen that may enter from other fields falls on plants that have already been pollinated with pollen that originated from plants within the field. In crops such as alfalfa, the hay cutting management schedule significantly limits or eliminates bloom, and thereby restricts the potential for pollen and/or viable seed formation.
- **The existence and/or degree of overlap in the pollination period of crops in adjacent fields varies.** This will vary depending on the maturity of crops, planting dates, and the weather. For corn, the typical pollen shed period lasts from 5 to 10 days for a particular field. Therefore, viable pollen from neighboring fields must be present when silks are receptive in the recipient field during this brief period to produce any grain with traits introduced by the out-of-field pollen.
- **Distance between fields of different varieties or hybrids of the same crop.** The greater the distance between fields the less likely their pollen will remain viable and have an opportunity to mix and produce an outcross. For wind-pollinated crops, most cross-pollination occurs within the

outermost few rows of the field. In fact, many white and waxy corn production contracts ask the grower to remove the outer 12 rows (30 ft.) of the field in order to remove most of the impurities that could result from crosspollination with nearby yellow dent corn. Furthermore, research has also shown that as fields become further separated, the incidence of wind-modulated cross-pollination drops rapidly. Essentially, the in-field pollen has an advantage over the pollen coming from other fields for receptive silks because of its volume and proximity to silks.

- **The distance pollen moves.** How far pollen can travel depends on many environmental factors including weather during pollination, especially wind direction and velocity, temperature, and humidity. For bee-pollinated crops, the grower's choice of pollinator species and apiary management practice may reduce field-to-field pollination potential. All these factors will vary from season to season, and some factors from day to day and from location to location.
- **For wind-pollinated crops, the orientation and width of the adjacent field in relation to the dominant wind direction.** Fields oriented upwind during pollination will show dramatically lower cross pollination for wind pollinated crops, like corn, compared to fields located downwind.

* * *

Roundup Ready Alfalfa

Product Description

Roundup Ready Alfalfa varieties contain in-plant tolerance to Roundup® agricultural herbicides,

enabling growers to apply labeled Roundup agricultural herbicides from planting through 5 days before cutting for unsurpassed weed control, excellent crop safety, and preservation of yield potential and quality.

Roundup Agricultural Over-The-Top Herbicide Products

Herbicide products sold by Monsanto for use over the top of Roundup Ready Alfalfa for the 2007 crop season are as follows:

- Roundup WeatherMAX
- Roundup Original MAX®

You may use another glyphosate herbicide, but only if it has federally approved label instructions for use over Roundup Ready Alfalfa, and the product and the use label for Roundup Ready Alfalfa have been approved by your specific state. Contact the product manufacturer, the local retailer, or the local extension agent for confirmation that the product carries EPA and state approved labeling for this use. MONSANTO DOES NOT MAKE ANY REPRESENTATIONS, WARRANTIES OR RECOMMENDATIONS CONCERNING THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES THAT ARE LABELED FOR USE OVER ROUNDUP READY ALFALFA. MONSANTO SPECIFICALLY DENIES ALL RESPONSIBILITY AND DISCLAIMS ANY LIABILITY FOR ANY DAMAGE FROM THE USE OF THESE PRODUCTS IN ROUNDUP READY ALFALFA. ALL QUESTIONS AND COMPLAINTS CAUSED BY THE USE OF GLYPHOSATE PRODUCTS SUPPLIED BY OTHER COMPANIES SHOULD BE

DIRECTED TO THE SUPPLIER OF THE PRODUCT IN QUESTION.

Tank mixtures of Roundup agricultural herbicides with other herbicides, insecticides, fungicides, micronutrients or foliar fertilizers may result in reduced weed control or crop injury. Refer to the Roundup agricultural herbicide product label, supplemental labeling, or fact sheets published separately by Monsanto for tank mix recommendations.

Please Note: To qualify for the alfalfa Stand Assurance component of Roundup Rewards®, labeled Roundup agricultural herbicides are the only systemic, non-selective herbicides which may be used for burndown and in-crop applications on any Roundup Ready Alfalfa crop on your farm.

For complete information about the use of Roundup agricultural herbicides over the top of Roundup Ready Alfalfa, refer to the appropriate Monsanto product's label booklet, or to supplemental labeling or fact sheets published separately by Monsanto. To learn more about applicable supplemental labels or fact sheets, call 1-800-ROUNDUP.

Certain Roundup agricultural herbicides referred to above may not be labeled for this application in your specific state. Please contact the manufacturer of this product, the local retailer, or the local extension agent for confirmation that this is an approved application.

Recommended Management Practices

Roundup Ready Alfalfa should be managed for high quality hay/forage production including timely cutting to promote high forage quality and to prevent seed

development. In geographies where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, Roundup Ready Alfalfa must be harvested at or before 10 percent bloom to minimize potential pollen flow from hay to common alfalfa seed production.

Roundup Ready Alfalfa varieties have excellent tolerance to over-the-top applications of labeled Roundup agricultural herbicides. An in-crop weed control program using Roundup WeatherMAX or Roundup Original MAX will provide excellent weed control in most situations. A residual herbicide labeled for use in alfalfa may also be applied preemergence, preplant, or postemergence in alfalfa. Contact a Monsanto Representative, local crop advisor, or extension specialist to determine the best option for your situation.

Stand Takeout and Volunteer Management

Crop rotations can be divided into two main groups, alfalfa rotated to: 1) grass crops (e.g. corn and cereal crops) and 2) broadleaf crops. More herbicide alternatives exist for management of volunteer alfalfa in grass crops. The recommended steps for controlling volunteer Roundup Ready® Alfalfa are:

Diligent Stand Takeout

Use appropriate commercially available herbicide treatments alone for reduced tillage systems or in combination with tillage to terminate the Roundup Ready Alfalfa stand. Refer to your regional technical

bulletin for specific stand takeout recommendations. Please note that Roundup agricultural herbicides are not effective for terminating Roundup Ready Alfalfa stands.

Start Clean

If necessary, utilize tillage and/or additional herbicide application(s) after stand takeout, and before planting of the subsequent rotational crop to manage any newly emerged or surviving alfalfa.

Plan for Success

Rotate to crops with known and available mechanical or herbicidal methods for managing volunteer alfalfa.

- Rotations to certain broadleaf crops are not advisable if the grower is not willing to implement recommended stand termination practices.
- In the event that no known mechanical or herbicidal methods are available to manage volunteer alfalfa in the desired rotational crop, it is suggested that a crop with established volunteer alfalfa management practices be introduced into the rotation.

Timely Execution

Implement in-crop mechanical or herbicide treatments for managing alfalfa volunteers in a timely manner; that is, before the volunteers become too large to control or begin to compete with the rotational crop.

Weed Resistance Management Guidelines

Follow the guidelines below to minimize the risk of developing glyphosate-resistant weed populations in a Roundup Ready Alfalfa System:

- Scout fields before and after each herbicide application.

- Start clean with a burndown herbicide or tillage.
- After emergence of the Roundup Ready Alfalfa stand, apply Roundup WeatherMAX® herbicide at a minimum of 22 oz/A at or before the 3 to 4 trifoliate growth stage.
- Use the right herbicide product at the right rate and at the right time.
- If new flushes of weeds occur, make additional applications of Roundup WeatherMAX herbicide at 22 to 44 oz/A before weeds exceed 6", up to 5 days before cutting—using the right rate for the weeds present.
- Include other herbicides where appropriate as part of a Roundup Ready Alfalfa weed control program.
- Report repeated non-performance to Monsanto or your local retailer.

Roundup Ready Alfalfa Stewardship

The Monsanto Technology/Stewardship Agreement (limited use license application) will be used and shall govern the terms and conditions for the authorized use of these products. All growers of Roundup Ready Alfalfa must also sign and comply with the Monsanto Technology/Stewardship Agreement (MTA). Due to special circumstances, alfalfa growers in the Imperial Valley of California will also sign an Imperial Valley Use Agreement (IVUA) with specific stewardship commitments.

Imperial Valley of California Use Agreement

Both the MTA or IVUA explicitly prohibit all forms of commercial seed harvest on the stand. Every alfalfa grower producing seed of Roundup Ready Alfalfa must possess an additional, separate, and distinct seed

grower contract to produce Roundup Ready Alfalfa seed.

Roundup Ready Alfalfa seed is for sale and distribution by authorized Seed Companies or their dealers for use in the United States only. This seed may not be planted outside of the United States, or for the production of seed, or sprouts. Any product produced from a Roundup Ready Alfalfa crop or seed, including hay and hay products, may only be used, exported to, processed, or sold in countries where regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.

Roundup Ready Alfalfa

Weed Control Recommendations

In both newly-seeded and established stands, to preserve the yield and quality potential of forage and hay, applications should be made after weeds have emerged but before alfalfa growth or re-growth interferes with application spray coverage of the target weeds.

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Preplant Burndown	Apply a prepaid burndown application of Roundup WeatherMAX at 16 to 44 oz/A. See the label for appropriate rates by weed species	Always start with a weed-free field. In no-till and reduced-till systems, apply a Roundup WeatherMAX burndown application to control existing weeds at least 1 to 2 weeks before planting.
Stand Establishment	An initial application of 22 to 44 oz/A of Roundup WeatherMAX should be applied at or before the 3 to 4 trifoliate growth stage. As necessary particularly in fall-seeded areas, a second application of up to 44 oz/A of Roundup WeatherMAX may be applied after the 5 trifoliate growth stage up to 5	**Note: Due to the genetic diversity of alfalfa, up to 10 percent of the seedlings are susceptible and will not survive the first application of Roundup WeatherMAX agricultural herbicides.** The initial application is necessary to eliminate the effects of stand gaps created by loss of

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
	days before the first cutting.	non Roundup Ready plants and to ensure adequate spray coverage of emerging weeds before crop canopy interference. Sequential applications should be at least 7 days apart.
Established Stands	After the first harvest of a newly established stand, up to 44 oz/A of Roundup WeatherMAX herbicide per cutting may be applied up to 5 days before each subsequent cutting.	Applications between cuttings may be applied as a single application or in multiple applications (e.g. 2 applications of 22 oz/A). Sequential applications should be at least 7 days apart.

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Weeds Controlled	For specific application rates and instructions for control of various annual and perennial weeds, refer to the Roundup WeatherMAX herbicide label booklet. Some weeds with multiple germination times or suppressed (stunted) weeds may require a second application of Roundup WeatherMAX herbicide for complete control. For some perennial weeds, repeated applications may be required to eliminate crop competition throughout the growing season.	In addition to those weeds listed in the Roundup WeatherMAX label booklets, this product will suppress or control the parasitic weed, dodder (*Cuscuta spp.*) in Roundup Ready Alfalfa. Repeat applications may be necessary for complete control. For tough to control weeds or weeds not controlled by Roundup® agricultural herbicides and labeled rates of other herbicides, alone or in tank mixtures, with Roundup agricultural herbicides.

PROGRAM	INSTRUCTIONS AND USE RATES	ADDITIONAL INFORMATION
Maximum Use Rates	**In-Crop:** • 44 oz/A per single application • Stand Establishment total: 88 oz/A - up to 44 oz/A before the 3 to 4 trifoliate growth stage. - plus, up to 44 oz/A up to 5 days before first cutting. • Established Stand Total: 44 oz/A per cutting up to 5 days before harvest.	**Total Per Year:** The combined total per year for all applications including pre-plant (stand establishment year) must not exceed 5.3 qt/A. The combined total per year for all in-crop applications in newly established and established stands must not exceed 132 oz/A (4.1 qt/A) of Roundup WeatherMAX

*If using another Roundup agricultural herbicide, you must refer to the label booklet or separately published Roundup Ready Alfalfa supplemental label for that brand to determine appropriate use rates. If using Roundup Original MAX®, application rates are the same as for Roundup WeatherMAX.

* * *

Roundup Ready® Alfalfa is for sale and distribution by authorized seed companies or their dealers in the United States only. Roundup Ready® Alfalfa seed may not be planted outside of the United States, or for the production of seed or sprouts. Any product produced from a Roundup Ready® Alfalfa crop or seed, including hay and hay products, may only be used, exported to, processed or sold in countries where regulatory approvals have been granted. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted. Roundup® agricultural herbicides are not yet approved in all states for use over-the-top with Roundup Ready® Alfalfa. Check with your Monsanto representative for the herbicide registration status in your state.

[Graphic omitted] Before opening a bag of seed, be sure to read, understand and accept the stewardship requirements, **including applicable refuge requirements for insect resistance management**, for the biotechnology traits expressed in the seed as set forth in the Monsanto Technology Agreement that you sign. By opening and using a bag of seed, you are reaffirming your obligation to comply with the most recent stewardship requirements.

[Graphic omitted] Grain harvested from products that bear this mark is fully approved for food and feed use in the United States and Japan, but is not approved in the European Union. You must find a market for this crop that will not ship this grain or its processed products to Europe. Appropriate markets

for this grain include: domestic feed use or grain handlers that specifically agree to accept this grain and handle it appropriately. For more information on your grain market options, go to the American Seed Trade Association's website at *www.amseed.org* or call your seed supplier.

MARKET CHOICES® is a registered certification mark used under license from ASTA.

Know Before You Grow®, an information service provided by National Corn Growers Association at *www.ncga.com*

Growers should refer to Monsanto's Technology Use Guide for information on crop stewardship regarding the potential movement of pollen to neighborhing crops. ALWAYS READ AND FOLLOW PESTICIDE LABEL DIRECTIONS. Know Before You Grow® is a registered service mark of National Corn Growers Association. For more information call 1-866-SELL CORN.

On April 18, 2005, the European Union (E.U.) notified that the following Monsanto corn traits already in the marketplace will be accepted (grandfathered) in processed feed: YieldGard Plus, YieldGard Rootworm with Roundup Ready Corn 2 and YieldGard Corn Borer with Roundup Ready Corn 2. This action by the E.U. on these biotech products may result in additional marketing options for growers who plant seeds containing these traits. Growers must talk to their grain handler to learn more and to determine whether this development affects their ability to market or their decision to plant these traits. YieldGard Plus with Roundup Ready Corn 2 was not in the market, and therefore not qualified to be notified by the E.U. for

acceptance in processed feed. Growers planting YieldGard Plus with Roundup Ready Corn 2 must talk to their grain handler to confirm the handler's buying position for grain from this product. It is a violation of national and international law to move material containing biotech traits across boundaries into nations where import is not permitted.

Always Read and Follow Pesticide Label Directions. Roundup Ready® crops contain genes that confer tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides. Roundup® agricultural herbicides will kill crops that are not tolerant to glyphosate. Bullet®, Degree®, Degree Xtra®, Field Master®, Harness®, INTRRO®, Lariat® and Micro-Tech® are restricted use pesticides and are not registered in all states. The distribution, sale or use of an unregistered pesticide is a violation of federal and/or state law and is strictly prohibited. Check with your local Monsanto dealer or Monsanto representative for the product registration status in your state. Bollgard®, Bollgard II®, Bullet®, Degree®, Degree Xtra®, Field Master®, Harness®, INTRRO®, Lariat®, Micro-Tech®, Roundup®, Roundup Original MAX®, Roundup Ready®, Roundup WeatherMAX®, YieldGard®, Monsanto imagine®, Roundup Rewards and the Vine Symbol and the vine symbol are registered trademarks of Monsanto Technology LLC. YUKON® is a registered trademark of Nissan Chemical Industries Ltd. All other trademarks are the property of their respective owners. ©2006 Monsanto Company. [15320pgd] 5A-9J-06-1631

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON SEED FARMS INC., et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	No. C-06-01075 CRB

DECLARATION OF NEIL HOFFMAN

I, Neil Hoffman, declare as follows:

I make the following representations based upon my personal knowledge and upon facts made known to me in my capacity as an official of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

1. I serve as the Director of the Environmental Risk Analysis Division for the USDA/APHIS' Biotechnology Regulatory Services (BRS). I have been in this position for approximately three and a half years. I have attached a copy of my curriculum vitae as Attachment 1.

Regulation of Genetically Engineered Plants

2. BRS is responsible for the regulation of the importation, interstate movement and release into the environment of genetically engineered (GE) plants.

3. Pursuant to regulations promulgated at 7 C.F.R. Part 340, BRS regulates the introduction of plants and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests in order to prevent the escape, spread, or establishment of plant pests.

4. These regulations allow the confined introduction of GE plants under conditions carefully designed to prevent escape and persistence in the environment. BRS can authorize introductions either under a permit (7 C.F.R. § 340.4) or a notification (7 C.F.R. § 340.3). The regulations also allow an applicant to petition BRS for a determination of nonregulated status (7 C.F.R. § 340.6), if the applicant believes that a regulated plant does not meet the definition of a plant pest.

5. To seek a determination of nonregulated status, the applicant must submit to BRS a petition containing the data specified in section 340.6(c). A regulated article may be granted nonregulated status only upon BRS' determination that it poses no plant pest risk.

Alfalfa Produced in the United States

6. Alfalfa is a perennial herbaceous legume that is grown worldwide, due to its adaptability to a wide range of climates. Alfalfa is grown as forage, where it is consumed by livestock in the field, and for hay, where the edible portions of the plant are mowed and removed for consumption as livestock feed. Alfalfa can be planted either in the spring or fall, depending on the climate and needs of the grower. Established alfalfa stands are typically mowed three to four times per year and can be productive for many years, depending

on climate and crop management Alfalfa hay is valued for its high levels of protein and other nutrients. Alfalfa hay is especially valued by the dairy industry because of its high calcium content. Hay quality is strongly influenced by crop maturity, and quality declines as flowering commences. Alfalfa is also grown for seed, the majority of which is planted to produce forage and hay. A small portion of alfalfa seed is used for human consumption, as alfalfa sprouts.

7. Growing alfalfa improves the nitrogen content of the soil in which it is planted, and most growers take advantage of this property by rotating alfalfa with other crops that can benefit from the increased soil fertility. Another reason growers plant alfalfa in rotation with other crops is that alfalfa exhibits autotoxicity, whereby alfalfa seeds do not germinate well in established alfalfa stands. Because of this effect, cleared alfalfa fields are not generally reseeded with alfalfa for at least one growing season. The germination of other crop seeds are not affected by alfalfa autotoxicity.

8. Alfalfa is insect pollinated, primarily by honeybees and leafcutter bees. Alfalfa's specialized flower can be pollinated only once, after which it is no longer available to insect pollinators. Producers of alfalfa seed frequently supplement native bee populations with beehives to ensure efficient pollination.

Genetically Engineered Roundup Ready® Alfalfa

9. BRS has many years of experience regulating glyphosate-tolerant Roundup Ready® alfalfa (RRA), which has been genetically engineered for tolerance to the herbicide glyphosate.

10. RRA is genetically engineered to be glyphosate tolerant by inserting a gene (from *Agrobacterium* sp. strain CP4) that codes for the enzyme 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) into the alfalfa genome. This gene, along with its regulatory sequences, was introduced into these alfalfa plants via an *Agrobacterium*-mediated transformation protocol. This is a well-characterized procedure, which has been widely used for over two decades for introducing genes of interest directly into plant genomes. BRS has previously granted nonregulated status to other GE glyphosate-tolerant crops, including corn, cotton, soybean, canola and sugarbeet.

11. APHIS first authorized the field testing of RRA in 1998 under its notification procedures (7 C.F.R. 340.3), and has authorized a total of 297 such field trials over a period of approximately eight years.

12. The developers of RRA, Monsanto Company (Monsanto) and Forage Genetics International (FGI), submitted design protocols in 1999 and 2000 that describe how field trials of RRA would be managed to comply with the performance standards required for all GE crops released under authorized notifications. These performance standards require that any field trials be conducted in a manner such that the GE plants are confined effectively and will not persist in the environment at the conclusion of the field trial.

13. The design protocols included maintaining a buffer zone of at least 900 feet between the RRA and other alfalfa, or keeping flowering plants in cages to preclude access to pollinators, or mowing alfalfa plantings to prevent the development of flower buds.

14. These protocols also required that any farm equipment used on RRA that could retain reproductive parts of the alfalfa plant had to be cleaned after use in the field where the RRA was grown, to avoid spreading reproductive parts to other areas. When field trials were terminated, RRA was destroyed using an appropriate herbicide, and the plant debris was incorporated into the soil by disking. Fields planted with RRA were monitored for a minimum of one full growing season after the termination of all field trials. Lastly, all fields used for the testing of RRA were clearly labeled for a full growing season after the termination of the field trial. Field trials of RRA were subject to routine inspections by BRS, and throughout the eight year period Monsanto and FGI maintained a good compliance record.

Granting Nonregulated Status To Roundup Ready® Alfalfa

15. On April 16, 2004, BRS received a petition from Monsanto and FGI requesting a determination of nonregulated status under RRA. On November 19, 2004, BRS completed its draft environmental assessment (EA). On November 24, 2004, a Notice was published in the *Federal Register* (69 FR 68300-68301), advising the public that BRS received Monsanto's petition, soliciting public comments on whether RRA presents a plant pest risk, and making available the EA for public comment. The comment period closed on January 24, 2005, but was reopened and extended to February 17, 2005, to provide interested parties additional time to comment (70 FR 5601-5602). BRS received 663 comments by the close of the extended comment period. There were 127 comments in support of the petition and 520 in opposition to the petition.

BRS finalized the EA and the Finding of No Significant Impact (FONSI) was signed on June 14, 2005. On June 27, 2005, BRS published in the *Federal Register* a Notice advising the public of its determination of nonregulated status, which was effective on June 14, 2005, and also announcing the availability of BRS' written determination document and FONSI. (70 FR 36917-36919). The decision to grant RRA nonregulated status was based, in part, on data included in the petition demonstrating that RRA posed no plant pest risk.

16. Since June 14, 2005, RRA has not been regulated by BRS under 7 C.F.R. Part 340. Therefore, after that date, RRA could be grown, sold, and processed in the United States without BRS oversight.

17. Plaintiffs filed this lawsuit on February 16, 2006, approximately eight months after BRS granted RRA nonregulated status.

18. Since being granted nonregulated status, there have been at least three planting cycles of RRA. Based upon information provided by Monsanto and FGI, approximately 220,000 acres of RRA have been planted by greater than 3,000 growers in 48 states since RRA was granted nonregulated status. Approximately 75 of these growers grow RRA for the production of alfalfa seed; the remainder are growing it exclusively for hay and forage. RRA constitutes approximately one percent of the total alfalfa acreage in the United States. Based on current sales, grower planting intentions, and available inventory, Monsanto would anticipate an additional 350,000 acres in new RRA forage production in 2007.

19. Because alfalfa stands are productive for many years, there are no commercial plantings of RRA old enough to justify destruction due to declining productivity.

Harm to Growers if RRA is Required to be Destroyed

20. The information presented below with respect to estimates of harm has been drawn from a variety of sources, including Monsanto and FGI, publically available information and information known to me in my capacity as an official of BRS. More comprehensive information regarding the extent of potential harm would need to be obtained from all of the affected agricultural sectors.

21. If growers of RRA were required to prematurely destroy their crop, they would suffer significant economic losses. The grower's investment in seed, fuel, fertilizer, pesticide, irrigation costs and labor is lost if the grower is unable to harvest alfalfa throughout the full usable lifespan of the crop. Most of these expenses are incurred in the first year of production to establish the crop while returns are realized over the ensuing years of production. Further, if a forage producers' crop is destroyed, the producer would be required to purchase livestock feed from another source. Persons who are growing RRA for hay would lose anticipated sales. As noted above, cleared alfalfa fields are not generally reseeded with alfalfa for at least one growing season. Therefore, growers forced to prematurely destroy their alfalfa may suffer loses attributable to growing an alternative crop.

22. Estimated data provided by Monsanto shows that to remove the existing RRA crop of 220,000 acres,

growers would lose an estimated $144,000,000 for expenditures in 2006 and lost production in 2007 based on a cost of $654 per acre assuming per acre costs as follows:

A. Equipment/labor (for crop destruction)	$ 50
B. Lost seed investment	$ 102 ($6/1b @ 17 lbs/acre)
C. Lost herbicide	$ 12
D. Lost production	$ 490 (5 tons/acre @ $140/ton minus $210 maintenance)

Maintenance costs are estimated from an economic analysis by the Oklahoma Cooperative Extension Service (OK Cooperative Extension Service Document Number E826 (http://www.okstate.edu/OSU_Ag/agedcm4h/pearl/e826/ch2.htm). Assuming similar production returns and maintenance costs, if farmers cannot plant RRA in 2008, they may lose up to $108,000,000 ($490/acre x 222,000).

23. If a grower is required to prematurely destroy an alfalfa planting, necessary equipment ordinarily leased by the grower may not be available at the time of the destruction. The fields may not be in a condition appropriate for cultivation at the time of destruction, thus resulting in degradation of soil quality, soil erosion, and other damage that could negatively impact the environment.

Harm to Growers if Future RRA Production is Enjoined

24. Growers who anticipated planting RRA will be unprepared for the coming growing season. Based on information provided by Monsanto and/or FGI, growers expect $100 to $200 per acre, on average, in

value over conventional alfalfa over the life of the RRA crop. New grower interest was high and current users anticipate increasing RRA acreage to approximately 570,000 total acres during the 2007 growing season. In anticipation of the spring 2007 planting season, growers may have already purchased their RRA seed and would have to substitute conventional seed if planting RRA in the next growing cycle is prohibited.

Harm to Monsanto and FGI if Future RRA Production is Enjoined

25. According to Monsanto and FGI, most of the seed produced in 2006 has been purchased by seed companies, distributors, dealers and/or growers. Without opportunity for planting, Monsanto and FGI seed companies and dealers will lose an economic return on seed investment of approximately $35,000,000. The value of the RRA seed to be harvested in fall 2007 is approximately $50,000,000. Also to be considered is the overall impact on the availability (See Appendix I, p. 328 of the petition, http://www.aphis.usda.gov/brs/aphisdocs/04 11001p.pdf) of alfalfa seed for planting over the next three years. Information submitted to BRS regarding seed production shows that production of commercial seed for alfalfa varieties is a multi-year process (up to three years minimum). FGI is the world's largest alfalfa seed production and breeding company. After being granted nonregulated status, the RRA could be freely crossed into different alfalfa varieties without BRS oversight. Significant resources have been devoted to breeding efforts targeted in developing varieties and increasing alfalfa seed that include the RR trait. Many of the seed producers have based varietal development plans on the assumption that

RRA will remain nonregulated. Seed producers and dealers would be forced to hold or destroy substantial inventories of RRA seed with immediate adverse impact on their businesses.

Harm to Exports if RRA Loses Nonregulated Status

26. Generally, countries will not allow importation of GE crops unless those crops have been granted nonregulated status or otherwise approved by the country of origin. If RRA is no longer considered a nonregulated article, alfalfa exports may be disrupted. Approximately 1.3 percent of the domestic alfalfa hay crop was exported in 2006. As the court noted, 75 percent of the alfalfa exported from the United States is exported to Japan. In March of 2006, Japan decided to allow the importation of RRA. If RRA is once again considered regulated by the United States, Japan may reconsider its decision. Even if exports of non-RRA were allowed to continue, foreign countries may require that alfalfa be tested for the presence of RRA which would cause exporters to incur costs associated with conducting the tests and evaluating the results. If foreign markets are closed, the unsold alfalfa could result in unexpected and harmful price fluctuations on the domestic market.

26. The uncertainty of the status of RRA will likely create general confusion and a lack of confidence among trading partners regarding past and future determinations of nonregulated status of GE plants by BRS. Acceptance of exports would be undermined and could result in enormous harm to growers who plant GE crops other than RRA. Importing countries may impose testing requirements for the presence of GE

traits, causing exporters to incur additional associated costs.

Risk of Gene Flow and Stewardship Practices —Likelihood of gene flow in alfalfa forage and hay production

28. The quality, and therefore the value, of alfalfa hay decreases with the onset of flowering and seed formation, and growers obtain significantly higher prices for hay cut prior to flowering as opposed to hay cut while plants are in full flower. Because of this price differential, alfalfa hay is often harvested prior to flowering and most always prior to seed set (Intermountain Alfalfa Management. UC Davis, Division of Agriculture and Natural Resources. Publication 3366, chapter 11. Harvest Management). According to statistics compiled in 2006, the price differential for high quality alfalfa was even greater for organic hay than for conventional hay, thereby encouraging mowing prior to flowering and seed set. (Alfalfa Hay 2006, CA Market Summary; http://www.ams.usda.gov/lsmnpubs/PDF_Monthly/2006CAHay.pdf).

29. Some pollen will be produced by fields harvested at 10% bloom, but this pollen has no effect on established plants. There is no biological means by which pollen can change the genetic constitution of an established plant. Pollen can fertilize the ovules within the flowers of existing plants to yield seeds with the GE trait. However, fields that do not produce seeds have no potential for gene flow and typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will produce any seeds.

30. According to Daniel Putnam, Extension Agronomist at University of California, Davis (Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf), gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage will be negligible for several reasons. First, flowering must be simultaneous between the proximate fields, and this is unlikely because there are many different alfalfa varieties, and they flower at different times. Second, sufficient pollinators must be present, they must move significantly between the two fields, and they must successfully transfer pollen from a flower in one field to a flower in another field. This series of events is unlikely because alfalfa grown for hay or forage is not stocked with bees to encourage pollination. Third, fertile embryos must mature into seeds, fall to the ground, and germinate, in spite of competition from mature alfalfa plants and the effects of autotoxicity, to contribute significantly to the dry matter of the subsequent hay crop.

31. Alfalfa is grown as a perennial crop for up to eight years. As long as seed used to plant the conventional or organic field is GE free, and the crop is managed for forage or hay, no measurable GE contamination should occur in the crop over the lifetime of that planting.

—Likelihood of gene flow from RRA forage fields to conventional seed fields

32. Intermingled alfalfa hay and alfalfa seed production only occurs in a few western states which

have the specific climate required for successful commercial seed production. Certified alfalfa seed production requires 165 feet of isolation from hay production employing other varieties. The isolation is inspected and verified by state seed certification organizations or an accredited organic certifier. Some conventional hay/forage fields are allowed to go to seed to produce "common seed." To minimize gene flow from RRA hay fields to common seed fields which are not certified, RRA hay growers are required to harvest at or before 10% bloom. (*See*, RRA stewardship practices, *infra*) As neither forage fields nor common seed fields are stocked with bees and forage fields contain few blooms to attract native pollinators, the potential for pollen-mediated gene flow to common seed fields is minimal.

33. Estimates of pollen-mediated gene flow from forage fields to seed fields have been made in a "worst case" forage management situation where the forage fields were allowed to flower more extensively than would commonly occur when alfalfa is managed for hay production. In addition, the seed fields were stocked with pollinators which also is not the usual practice for common seed production. In one case flowering was allowed to occur to 50% bloom in a neighboring hay field and leaf cutter bees were used to pollinate seed fields situated at increasing distances from the flowering field. In this case gene flow was 0.2% at both 150 and 300 feet. In a second study, flowering in the neighboring hay field was allowed to occur to 20% bloom and honey bees were used to pollinate the seed field. In this case, gene flow was 0.29% at 165 feet, 0.16% at 215 feet, 0.15% at 315 feet and was rarely

detected (0.00 to 0.05%) at distances greater than 350 ft.

—Likelihood of gene flow in alfalfa seed production

34. Approximately 18,000 acres of RRA have been planted for seed production since June, 2005, when RRA was granted nonregulated status.

35. An alfalfa pollen flow study was conducted during the summer of 2000 by FGI, in association with members of the Regulatory Affairs Committee of the North American Alfalfa Improvement Conference (McCaslin, M. and S. Fitzpatrick 2000, 37th NAAIC proceedings, pp. 396-400). Fields were stocked with leaf cutter bees and also contained native honey bees. Pollen flow was estimated as 1.39, 0.32, 0.07, and 0.00 percent at 500, 1000, 1500, and 2000 feet, respectively. Results from this experiment indicate that gene flow will be under 0.5% in adjacent alfalfa fields if isolation distances of 900 feet are maintained when leaf cutter bees are used as the pollinator.

36. Leaf cutter bees are the predominant pollinator for alfalfa in all western states except California where honeybees are used instead.

37. An alfalfa pollen flow study was conducted during the summer of 2002 in California by University of California, Davis, FGI and Monsanto. Fields were stocked with honeybees. Pollen flow was estimated as 1.49, 1, 0.2, and under 0.06 percent, at 900, 3000, 5000, and 10,000 feet, respectively. Results from this study indicate that gene flow will be under 0.1% in adjacent alfalfa fields if isolation distances of 3 miles are maintained when honey bees are used as the pollinator.

—RRA stewardship practices

38. To facilitate coexistence between RRA growers and other alfalfa growers, Monsanto and/or FGI require all RRA growers to sign an agreement which requires the RRA grower to follow strict stewardship practices. All seed purchasers, dealers, distributors, producers and processors of RRA seed must be licensed by Monsanto and agree to comply with such stewardship practices. Therefore, Monsanto and/or FGI have records of all growers and site locations of RRA in the United States.

39. Forage growers are provided with online training modules. Grower agreements limit planting of purchased seed to the United States and obligate all participants to limit seed use to the planting of RRA for hay and forage (seed production is prohibited). In areas where conventional common alfalfa seed production is intermingled with forage production and the agronomic conditions (climate and water/irrigation availability) are such that forage alfalfa is allowed to stand and flower late in the season, RRA must be harvested at or before 10% bloom to minimize potential pollen flow from hay to common alfalfa seed production.

40. All growers who purchase RRA in states where alfalfa seed is produced are required to report to Monsanto the field locations and global positioning coordinates for any field planting of RRA. Alfalfa seed-producing states include the following 17 states; AZ, CA, CO, ID, KS, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WY. This information is intended to be used to audit forage producers to ensure that no unauthorized seed production is occurring and that they are mowing their hay prior to 10% bloom.

Following the first year of launch, Monsanto will conduct on farm spot checks and contacts growers to ensure compliance with the limited-use license agreement. Failure to comply with that license or the stewardship requirements will result in termination of an RRA grower's limited-use license and a restriction on the future use of Monsanto products.

41. All seed production is sub-contracted through FGI. All growers receive annual training and on-farm support. FGI requires that all growers of RRA seed be under a seed production contract for each variety. Contract seed growers are prohibited from selling RRA variety seed into "common" or "VNS" seed channels. Foundation seed standards are the standards established by the Association of Official Seed Certifying Agencies (AOSCA). FGI requires foundation seed standards for isolation (900 feet) in areas where leaf cutter bees are used for pollination and 3 miles in areas where honey bees are used (e.g., in California). Isolation distances are verified by state crop improvement associations. In the western United States, where hay and seed are both produced, licensees must identify the exact field location where RRA seed will be planted. Monsanto monitors for potential violations.

42. Harvested seed is placed in unique RRA seed bins. RRA seeds have a unique purple seed coating to distinguish them from conventional varieties and seed is processed under license only in a limited number of facilities. Seed bags are labeled "Roundup Ready® alfalfa." All seed purchasers, dealers, distributors, producers, and processors of RRA seed are licensed through Monsanto.

43. FGI seed growers report all RRA seed production field locations to state crop improvement associations to facilitate the industry's management of field history and isolation information. FGI grows all RRA variety seed in the United States using AOSCA and/or Organization for Economic Cooperation and Development certification standards.

44. Seed producer contracts prohibit the sale of RRA seed for sprouting (food) use. However, food safety consultation with the United States Food and Drug Administration were completed and covered the incidental inadvertent presence of the RRA trait in seed used for sprouting purposes.

45. To support buyer-seller agreements that may stipulate conditions for GE trait status, trait detection strips are readily available for alfalfa seed and hay product and are simple to use.

46. For the reasons stated above, I believe that gene flow is negligible between hay fields due to (1) the biology of alfalfa plants; (2) management practices driven by the value and quality of the crop; and (3) stewardship requirements imposed by Monsanto and FGI. Accordingly, there is little possibility of harm to plaintiffs.

BRS' Ability to Re-Regulate RRA

47. BRS approves a petition for nonregulated status when it concludes that the GE plant poses no plant pest risk. Once BRS has granted nonregulated status, the GE plant may be freely moved and planted without the requirement of permits or other regulatory oversight. In this case, BRS determined that RRA poses no plant pest risk, no information has become available subsequently to alter that conclusion, and the

opinion of the Court in this case does not set aside that determination. In the administrative record and the record of this proceeding, there is no demonstrated threat of harm to plant health, human health or livestock health from RRA.

48. If BRS were required to fully re-regulate the RRA that has been planted to date, it would pose significant practical difficulties. The current permitting system is designed to regulate small scale field tests and plants are required to be destroyed at the conclusion of the field tests. Issuing permits for 220,000 acres of RRA planted for forage/hay production would be impracticable. The inspection of such large acreage under permit would pose unusual challenges to BRS' current regulatory structure and significantly drain BRS resources. Furthermore, BRS would be responsible for issuing permits for the interstate movement of all hay, seeds and other RRA products produced on the thousands of acres of RRA grown under permit.

49. Further, as a policy matter, because BRS' determination that RRA poses no plant pest risk is still operative, it would be illogical to regulate RRA pursuant to a permitting scheme that is designed to mitigate plant pest risks. In accordance with this Court's opinion, BRS is fully committed to prepare a comprehensive environmental impact statement prior to deciding in the future whether RRA should be unconditionally deregulated. BRS believes that it would take approximately two years to complete the environmental impact statement. In the interim period, BRS proposes that RRA should be allowed to be grown, harvested and used, but only in accordance with the following stringent, science-based

requirements which are designed to address the potential environmental harms identified by plaintiffs and this Court. This course of action is consistent with the determination that RRA is not a plant pest and would be less likely to result in foreign trade disruptions.

50. BRS proposes the following conditions for RRA planted after the date of this judgment:

a. Isolation distances between RRA and alfalfa seed production fields will be required to mitigate any potential pollen flow;

b. Specific harvesting conditions for RRA fields will be required to minimize cross pollination in areas where growers are producing alfalfa seed;

c. Cleaning of planting and harvesting equipment will be required after contact with RRA prior to its use on non-RRA alfalfa;

d. Identification and handling requirements for RRA seed before and after harvest;

e. All RRA seed producers and hay growers must be under contract, with Monsanto and/or FGI and the contracts must require compliance with the four preceding conditions and these conditions must be followed for the entire life of the RRA stand; and.

f. No RRA can be used for livestock grazing purposes or in a mixed grass pasture.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 2nd day of March, 2007, in Riverdale, MD.

s/ Neil Hoffman

NEIL HOFFMAN

NEIL HOFFMAN, Ph.D

EDUCATION

Ph.D., Plant Physiology, University of California, Davis, CA, 1982

- Thesis: Regulation of Ethylene Biosynthesis

B.Sc., Biology, Cornell University, Ithaca, NY, 1978

EXPERIENCE

USDA. Animal Plant Health Inspection Service. Biotechnology Regulatory Services.
Riverdale, MD. **2003-present**
Director of Environmental Risk Analysis Division.

NATIONAL SCIENCE FOUNDATION, Arlington, VA. **2002-2003**
Program Director, Division of Cellular and Molecular Biology

PARADIGM GENETICS, RTP, NC **1999 - 2002**
Senior Staff Scientist/Manager of Plant Physiology and Biochemistty

CARNEGIE INSTITUTION of WASHINGTON, Stanford, CA **1988 -1999**
Associate Professor of Plant Biology, Stanford University, Dept. of Biology 1996 - 1999
Assistant Professor of Plant Biology, Stanford University, Dept of Biology 1988 - 1996

- Identified by the Institute for Scientific Information as a highly cited researcher in plant and animal science.

ROCKEFELLER UNIVERSITY, New York, NY & **UNIVERSITY of PENNSYLVANIA,** Department of Biology, Philadelphia, PA **1986 - 1988**
NSF Postdoctoral Fellow with Anthony Cashmore

JA-365

MICHIGAN STATE UNIVERSITY, Plant Research Lab, E. Lansing, MI **1983 - 1986**

Postdoctoral Research Associate with Andrew Hanson

ADDENDUM

Invited Lectures

Food Products Association Spring Meeting, Arlington, VA May 10, 2006

University of Maryland University College Biotechnology Symposium. Rockville, MD. May 4, 2006

Western Plant Board. Monterey, CA. May 2, 2006

National Science Foundation. Arlington, VA. Feb. 28, 2006.

American Biological Safety Association, San Antonio, TX, October 16, 2004

Biosafety Institute for Genetically Modified Agricultural Products, Ames IA, April 22, 2004
University of VA, Richmond, Richmond VA,

Plantgenix, Philadelphia, PA Feb. 27, 2002.

National Science Foundation, Arlington, VA. Feb. 15, 2002

Danforth Plant Science Center, St. Louis, MO. April 27, 2001

Institut de Biologie Physico-Chimique, Paris, France Feb. 13, 1999

CNRS, Grenoble, France, Feb. 9, 1999

Commissariat a la Energie Atomique, Cadarache, France Feb. 8, 1999

European Research Conference on Protein Targeting, Obernai, France, Feb 3, 1999

Annual Meeting, American Society of Plant Physiologists, Baltimore, July 26, 1999

University of Texas, Austin, April 8, 1999

University of Arkansas, Fayetteville, April 6, 1999

USDA, Albany, CA, Feb. 17, 1999

Western Photosynthesis Congress, Asilomar, CA. Jan. 9, 1999

Hoffman La-Roche, Nutley, NJ, December 18, 1998

University of California, Los Angeles, CA. Dec. 4, 1998

Paradigm Genetics, Research Triangle Park, NC, Dec. 3, 1998

Dow Agro, Indianapolis IA, Nov 19, 1998

Cereon Genomics, Cambridge Mass., October 26, 1998

Intl Congress on Photosynthesis, Budapest, Hungary, Aug. 19, 1998

Dupont Agricultural Experiment Station, Wilmington, DE July 23, 1998

Maxygen, Santa Clara, CA. July 15, 1998

University of Kyoto, Kyoto, Japan, Feb 26, 1998

University of Tokyo, Komaba Campus, Feb. 24, 1998

University of Tokyo, Hongo Campus, Feb. 23, 1998

Keynote Lecture, Photosynthetic Membranes: Biogenesis and Adaption. Vancouver, 7/31/1997

Yale University, New Haven CT. July 18, 1997

University of Pennsylvania, Philadelphia, PA April 17, 1997

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IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS INC., et al.	)	Case No. C-06-1075 (CRB) (EDL)
Plaintiffs,	)	JUDGMENT IN A
vs.	)	CIVIL CASE
MIKE JOHANNS, et al.,	)	
Defendants	)	

IT IS ORDERED AND ADJUDGED that, pursuant to the Memorandum and Order filed 13 February 2007 ("Order"), judgment is entered (1) in favor of plaintiffs' as to their First Claim and Second Claim and (2) in favor of defendants ("APHIS") as to plaintiffs' Third Claim, Fourth Claim, Fifth Claim, and Sixth Claim. The Court dismisses plaintiffs' Fourth Claim with prejudice; it dismisses plaintiffs' Third Claim, Fifth Claim, and Sixth Claim without prejudice.

Pursuant to the Order, defendants' 14 June 2005 Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate is hereby vacated. Before making any further decision whether to approve nonregulated status, APHIS shall prepare an environmental impact statement ("EIS").

APHIS shall complete such EIS within two years after the date of entry of this Judgment. Until then, the growing and use of the J101 and J163 alfalfa

challenged here ("challenged alfalfa") shall be subject to the following provisions:

First, APHIS adopted its nonregulated status decision on 14 June 2005; plaintiffs filed their Complaint on 16 February 2006. In the interim, and during the pendency of this lawsuit, farmers and others planted the challenged alfalfa for both forage production and seed production on properties not specified in the administrative record. Therefore, for challenged alfalfa introduced before the date of entry of this Judgment, this Court cannot practically order a remedy or otherwise restrict this alfalfa. This Judgment does not require any person who planted the challenged alfalfa between 14 June 2005 and the date of entry of this Judgment to remove or destroy the plants or seeds, and it does not restrict the use of the harvested forage or movement of harvested seed by seed producers to Monsanto or Forage Genetics, Inc. Further, nothing in this Judgment requires regulation by APHIS of any challenged alfalfa planted between 14 June 2005 and the date of this judgment.

Second, the challenged alfalfa may be introduced after the date of entry of this judgment but subject to the following conditions: (1) Isolation distances between challenged alfalfa and alfalfa seed production fields will be required to mitigate any potential pollen flow; (2) Specific harvesting conditions for challenged alfalfa fields will be required to minimize cross pollination in areas where growers are producing alfalfa seed; (3) Cleaning of planting and harvesting equipment will be required after contact with challenged alfalfa prior to its use on non-challenged alfalfa; (4) Identification and handling requirements will apply to challenged alfalfa seed before and after

harvest; (5) All challenged alfalfa seed producers and hay growers must be under contract with Monsanto and/or Forage Genetics Inc., the contracts must require compliance with the four preceding conditions and these conditions must be followed for the entire life of the challenged alfalfa stand; and (6) No challenged alfalfa can be used for livestock grazing purposes or in a mixed grass pasture. APHIS shall provide further specification of such conditions and publish a notice of such specification in the Federal Register.

Charles R. Breyer
United States District Judge

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF PHILLIP
vs.	) GEERTSON IN SUPPORT OF
MIKE JOHANNS, et al.	) PLAINTIFFS PERMANENT
Defendants,	) INJUNCTION, FINAL RELIEF, AND ENTRY OF JUDGMENT

I, Phillip Geertson, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I prepared a Declaration in Support of Plaintiffs' Motion for Summary Judgment, and hereby incorporate that declaration herein.

3. I reside at 21017 Cottonwood Street, Greenleaf, Idaho 83626.

4. My wife and I do business as Geertson Seed Farms, an Oregon business. Geertson Seed Farms contracts with other farmers to grow seed which we sell. Geertson Seed Farms operates a seed cleaning plant. I market eight varieties of alfalfa seeds my farm and contracted growers produce directly to growers both domestically and internationally. I have sold seed direct to alfalfa forage growers for over thirty years. I

have been associated with a plant breeding program for over twenty years. As part of my work, I talk to alfalfa forage farmers all over the country. I have been concerned about the development of Roundup Ready alfalfa for several years.

5. My father grew alfalfa seed beginning in 1939 and our family still farms the land that my family homesteaded in 1939. I fear that genetically engineered alfalfa will adversely affect the environment and affect the ability of conventional farmers to grow their crop. We have raised alfalfa seed for 40 years.

6. Allowing the planting of Roundup Ready alfalfa is particularly threatening to non-Roundup Ready alfalfa crops because it is an open pollinated crops—bees carry its pollen long distances—and because it is a perennial that persists in the ground for 3 to 8 years.

7. In addition the fact that alfalfa is a perennial crop that grows for up to 8 years, alfalfa has a high percentage of hard seed. Up to 50 % of alfalfa seed is hard seed. Hard seed is seed that can last in the ground without germination for more than 20 years. For example, if Roundup Ready seed was plowed under the ground deeply, the hard seed could remain dormant for many years. Then, some years later, if that hard seed was brought back to the surface through plowing, the Roundup Ready hard seed could germinate and begin growing again.

8. A recent study undertaken by Bob Hammon et al., "Pollen Movement from Alfalfa Seed Production Fields," scientifically documented that alfalfa contamination in fact occurs in the agricultural environment. (Attachment 1.) The study harvested

feral alfalfa seed at varying distances from Roundup Ready alfalfa seed fields to determine the distance and extent that contamination can occur from pollen carrying bees. The furthest test sight sampled for the study was 1.7 miles from the Roundup Ready alfalfa fields. At 1.7 miles away, contamination with the Roundup Ready alfalfa was 3.8%. This is a very high concentration, considering that no legal tolerances for non-Roundup Ready have been set, and that some markets unofficially allow for seed sales with minimal contamination ranging from 0-1%. The study concluded that "the farthest distance they [bees] can move pollen cannot be determined from this project because we found the RR gene at our most distant site from the pollen source." This study shows me that contamination may be greater than we previously understood.

9. Based on the results of this study and my experience as an alfalfa grower for 20 years, I am confident that if Roundup Ready alfalfa is planted this year, all non-Roundup Ready alfalfa will be contaminated in just a few short years.

10. Planting of Roundup Ready alfalfa in the U.S. will destroy the foreign seed market for U.S. seed growers, causing oversupply of U.S. seed that is contaminated by the Round-up ready gene. Raising alfalfa seed in the U.S. that is free of contamination will be nearly impossible. Most foreign buyers of alfalfa seed will not accept alfalfa contaminated with the Roundup Ready gene.

11. It is important that the sale and planting of Roundup Ready alfalfa seed be stopped until a full Environmental Impact Statement is completed.

12. Alfalfa seed can remain viable, with marketable germination rates, for at least up to 7 years if stored properly in warehouses. If alfalfa seed is stored in cold storage facilities, alfalfa seed can remain viable, with marketable germination rates, for 20 years or longer.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 1, 2007, in Greenleaf, ID.

/s/
Phillip Geertson

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

JA-383

Pollen Movement from Alfalfa Seed Production Fields

Bob Hammon, Carrie Rinderle, and Melissa Franklin
Colorado State University Cooperative Extension, Tri River Area, P.O. Box 20,000-5028, Grand Junction CO 81502-5028; (970) 244-1834; contact: bob.hammon@mesacounty.us

Abstract

An alfalfa pollen flow study was conducted near Fruita, CO (Mesa Co.) during the summer of 2006 with he objectives of determining the distance that bees transport Roundup Ready® alfalfa pollen under local field conditions, and estimating the role alkali bees play in alfalfa pollen transport in the area. We harvested seed from feral alfalfa plants at 23 sites on roadsides, abandoned fields, and edges of active hay fields within two miles of Roundup Ready® alfalfa seed fields. We also collected bees from these sites throughout the alfalfa bloom season to determine which species were moving pollen. The harvested seed was planted and seedlings treated with Roundup® to assay for the presence of the Roundup Ready® gene. The gene was found at 83% of the collection sites, out to a distance of 1.7 miles from the pollen source. Alfalfa leafcutter bees and honey bees were the most common bees collected at the seed harvest sites. Honey bees appeared to be the most important bee involved in long distance pollen transport. More *Melissodes* and *Anthophora* species than alkali bees were captured at the seed collection sites. Alkali bees played a minor role in long distance transport of pollen under these conditions.

Introduction

Roundup Ready® (RR) alfalfa is grown for seed on approximately 900 acres of land near Fruita, Colorado (Mesa County). It has been produced in the area since 2004. These seed production fields are pollinated primarily by managed alfalfa leafcutter bees, *Megachile rotundata*, but many native bees, including alkali bees, *Nomia melanderi*, are present in the fields. Several alkali bee nesting sites are known in the vicinity of the RR seed production fields, and alkali bees are at times very common in the area. Table 1 lists bee species that have been captured in alfalfa seed production fields near Fruita.

We conducted a research program in 2006 to:

1) Determine the distance that RR pollen is moving from alfalfa seed production fields.
2) Estimate the role of alkali bees in pollen movement from the seed production fields.
3) Determine which bee species were active in moving RR pollen from seed production fields.

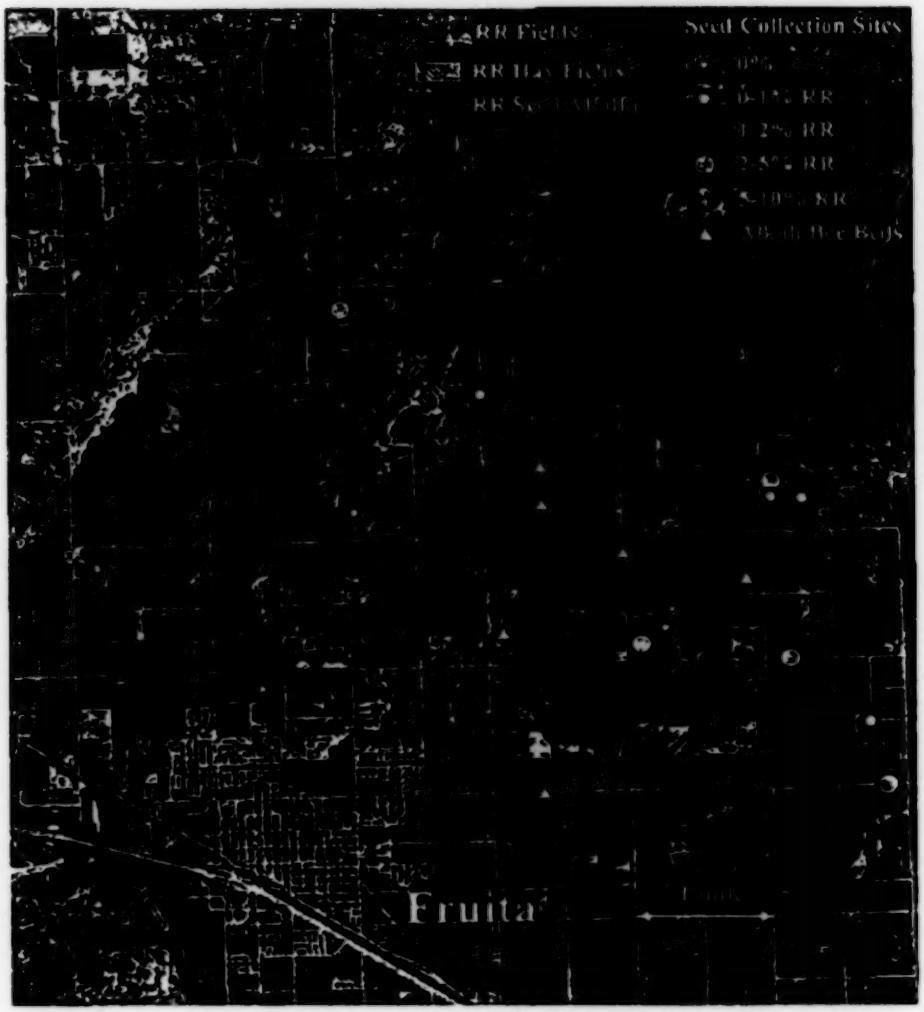

Figure 1. Location of RR seed fields (red) and hay fields (pink), seed collection sites (circles coded by amount of RR seed found), and alkali bee beds.

Methods

The RR fields we used as the study site are located approximately 2 miles NW of Fruita CO. They are isolated from other RR alfalfa seed production by 7 miles of open farm and range land. There were several RR alfalfa hay fields planted in the area in the fall of 2005 and spring of 2006. First and second cuttings in

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these fields were taken no later than early bloom growth stage, so the amount of RR pollen from these fields was relatively small and present only for a few days. For the purposes of this study we assumed that the RR alfalfa seed production fields were the sole source of RR pollen. Figure 1 shows the location of RR seed production fields and RR alfalfa hay fields in the study area.

We located sites in the area where feral alfalfa plants produced seed. The sites were at different directions and distances from seed production fields. Distances to seed fields were measured on a straight line basis, using aerial photographs imported into ArcMap 9.1. Our most distant site was 1.7 miles from the nearest seed field. Seed was collected from 23 sites.

The seed collection sites were located on roadsides, field edges, and waste areas. Except for a single site, no extra management was taken to allow them to produce seed Site locations, descriptions and distances from RR seed production fields are listed in Table2.

We gathered seed as soon as enough was mature enough to allow for collection of about 1000 seeds. At ten sites, we collected on two dates to determine the amount of mid and late summer pollen flow.

Seed was cleaned in the lab at the Western Colorado Research Center at Fruita. The cleaned seed was sent to Forage Genetics, Nampa ID where it was assayed for the RR gene. They planted the seed in flats, counted the seedlings then sprayed them two times with Roundup® herbicide. The survivors were then counted as an assay for the RR gene. A number of randomly chosen survivors were tested for the RR

gene using SDI test strips to test for the presence of the CP-4 gene.

Bees were collected from the seed production fields and seed collection sites on a regular basis, beginning with first bloom in late May. The primary objectives were to find alkali bees and to document the diversity of bees in the area. The collected bees were taken to the USDA Bee Lab in Logan, UT for identification.

It is important to note that the bee collections are not a quantitative representation of species we saw in the field. We quit collecting honey bees and leafcutter bees because they were so common. The focus of the collection was the other bee species, so honey and leafcutter bees are under-represented in the collection. Bees captured at the seed collection sites are pictured in Figure 2.

Results

The results of the RR seed assays are presented in Table 2 and Figure 1. Seedlings that survived the Roundup® application in the bioassay tested positive for the CP-4 gene, so all surviving seedlings were considered RR. The RR gene was found at 19 of 23 seed collection sites. The percentage of RR seed at sites where it was present ranged from 0.18 to 9.46%.

There was no correlation between distance from RR pollen source and the percent RR seed.

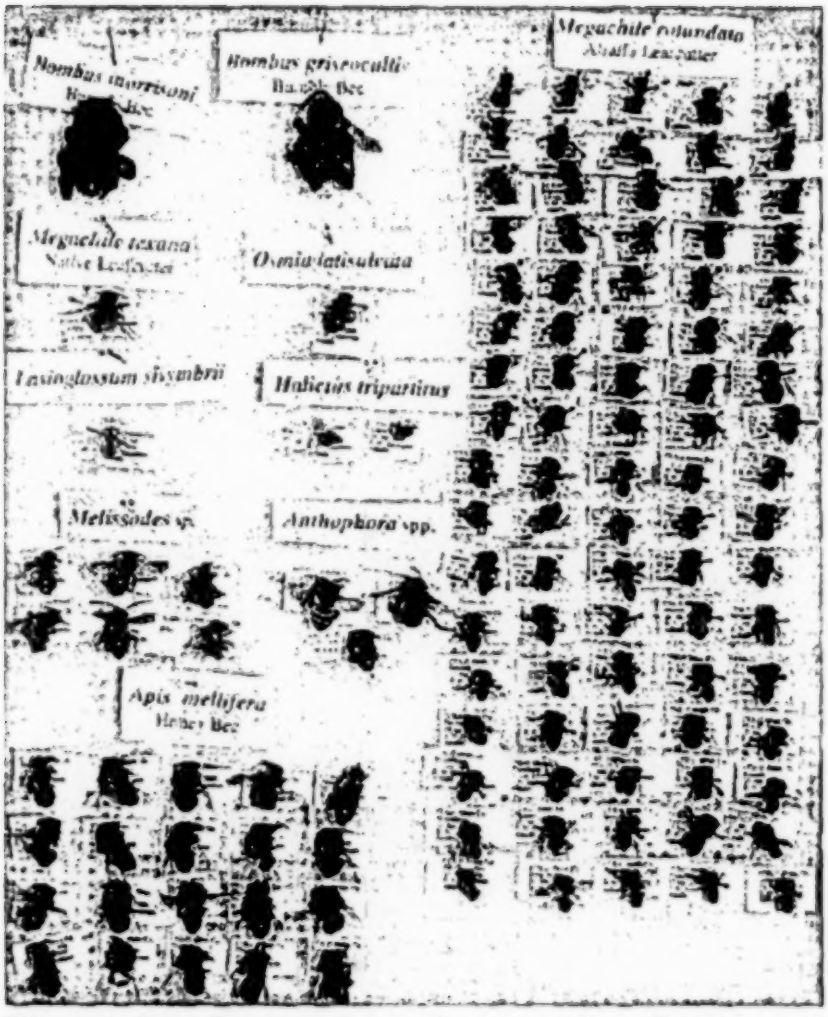

Figure 2. Bees captured at seed collection sites. Leafcutter and honey bees dominated the captures at all sites.

There was significant early season movement of the RR gene. Seed collected as early as mid-July had 0.4% RR genetics present. Two of these sites were within 0.5 mile of the RR pollen source. Leafcutter bees were common at these sites and they were probably responsible for most of the short-distance early season

pollen flow. We caught alfalfa leafcutter bees at seed collection sites a full two weeks before managed bees were released into local shelters at seed production fields.

Female alkali bees did not emerge until June 22nd, with the peak of the emergence in late June and early July. The time span between pollination and seed maturity is about 28 days, so movement of the RR gene to seed collected before late July could not have been by alkali bees. One collection site (#26) was located within 200 yards of an alkali bee bed, and tested more than 5% RR seed. This site was 0.5 mile from a RR seed field. A second collection site (#11) was also about 100 yards from an alkali bee bed, but tested only 1.5% positive for RR seed, even though it was only 0.4 miles from a seed field. The mere presence of alkali bees nesting areas in the area did not guarantee high amounts of RR pollen movement.

The percentage of RR seed was apparently unchanged from the first to second seed collection date at 5 of the ten sites that were sampled twice. All of the pollen movement occurred before mid July at four of these sites.

Alfalfa leafcutter bees and honey bees were the dominant species taken while sampling bee populations. Previous research has shown that alfalfa leafcutter bees do not transport pollen over distances greater than one mile under most conditions. Honey bees are known to be capable of transporting pollen more than one mile. The other bees taken in the collections that would be capable of transporting pollen to the furthest seed collection site are bumble bees (*Bombus morrisoni* and *B. griseocullis*), *Melissodes*

sp., *Anthophora* spp., and *Osmia latisulcata*. Only one alkali bee was taken at a remote seed collection site, although five nesting sites were found in the area. We must assume that most alkali bee foraging was within seed fields or local in nature.

Table 1. Bees found in Fruita CO alfalfa seed production fields. Bees are listed in approximate order of abundance in fields limited to the seed production fields.

Megachile rotundata	Alfalfa leafcutter
Apis melifera	Honey bee
Nomia melanderi	Alkali bee
Melissodes sp	
Anthophora spp (2)	Digger bees
Bombus morrisoni	Bumblebee
Bombus griseocullis	Bumblebee
Lasioglossum sisymbrii	
Halictus tripartitus	
Halictus confusus	
Megachile texana	Leafcutter bee
Osmia latisulcata	

Conclusions

Bees are capable of moving the RR gene at least 1.7 miles. The farthest distance they can move pollen

cannot be determined from this project because we found the RR gene at our most distant site from the pollen source. Pollen movement at the furthest site occurred late in the season, since the 8/11 seed collection had no RR seed, while the 9/19 collection had 3.8% RR seed.

Alkali bees were probably of minor importance in long distance pollen movement. *Melissodes* sp., *Anthophora* spp., and *Bombus* spp. were more common in collections than alkali bees. Several other taxa of native bees including *Megachile* spp., *Osmia latisculata*, *Lasioglossum* sp., and *Halictus* sp. are responsible for short and mid range movement of pollen.

Honey bees were probably the most important species involved in long-distance pollen transport. Most of these bees are apparently feral since only one hobby beekeeper could be located in the area.

Acknowledgements

This project was funded by Forage Genetics, Nampa ID, and conducted in cooperation with Waters Farms, Fruita CO. Dr Jim Cane and Terry Griswald, USDA/ARS Logan Bee Lab assisted with bee identification. Several Fruita area landowners allowed us access to their property for alfalfa seed collection. We are grateful to all who assisted us.

Table 1. Seed collection site descriptions and RR assay results.

[1] N is the number of alfalfa seedlings tested for the RR gene in bioassays.

		G.P.S.			Collection Dates					
Site	Description	North	West	Distance	1st	% RR	N [1]	2nd	% RR	N
1	Edge of active field	39.233	108.716	0.84	7/10	0.00%	305	9/7	0.00%	51
2	Edge of active field	39.176	108.668	0.44	7/12	0.18%	552	8/16	0.41%	726
3	Edge of active field	39.171	108.650	0.30	7/13	0.42%	475	8/30	1.07%	656
4	Abandoned field	39.209	108.701	0.47	7/28	1.06%	470			
5	Abandoned field	39.197	108.658	0.87	7/26	1.21%	829	9/7	1.40%	358
6	Edge of active field	39.199	108.662	0.72	7/27	0.20%	503	9/7		
7	Edge of active field	39.199	108.661	0.81	7/27	2.81%	178	9/7		
8	Edge of active field	39.197	108.662	0.66	7/27	0.27%	374	9/7		

Site	Description	G.P.S. North	G.P.S. West	Distance	Collection Dates 1st	% RR	N [1]	2nd	% RR	N
9	Edge of active field	39.233	108.713	0.65	7/26	0.00%	219			
10	Edge of active field	39.233	108.714	0.73	7/28	0.00%	238	8/16		
11	Edge of active field	39.179	108.697	0.43	7/31	0.70%	1002	9/7	1.50%	467
12	Roadside	39.207	108.701	0.33	8/10	9.46%	560	8/16	9.17%	1669
13	Roadside	39.203	108.701	0.25	8/11	4.50%	977	9/19	4.05%	469
14	Abandon field	39.212	108.729	1.68	8/11	0.00%	398	9/19	3.78%	608
15	Edge of active field	39.170	108.655	0.02	8/11	3.29%	821			
16	Roadside	39.209	108.720	1.31	8/11	0.00%	820	9/19	0.00%	539
20	Abandon property	39.219	108.720	1.04	9/7	0.25%	800			
21	Abandoned field	39.188	108.710	0.28	9/7	0.58%	693			
23	Edge of active field	39.164	108.648	0.40	8/30	1.58%	506	9/25	0.96%	313

Site	Description	G.P.S. North	G.P.S. West	Distance	Collection Dates 1st	% RR	N [1]	2nd	% RR	N
24	Abandoned field	39.179	108.660	0.51	8/30	2.23%	764			
26	Roadside	39.189	108.664	0.52	9/7	5.08%	610			
27	Roadside	39.181	108.680	0.26	9/19	2.43%	823			
28	Abandoned field	39.193	108.699	0.15	9/25	2.03%				

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.	)	Case No. C06-1075 CRB
Plaintiffs	)	DECLARATION OF
vs.	)	WILLIAM B. ROSTOV
	)	IN SUPPORT OF
MIKE JOHANNS, et al.	)	PLAINTIFFS'
Defendants	)	MOTION FOR
	)	PERMANENT
	)	INJUNCTION, FINAL
	)	RELIEF, AND
	)	ENTRY OF
	)	JUDGMENT

I, William B. Rostov, do hereby declare as follows:

1. I am an attorney admitted to practice law in California. I am a senior attorney with Plaintiff Center for Food Safety and counsel for Plaintiffs in this action. I make this declaration based upon my own personal knowledge and if called upon to testify, could and would do so competently.

2. Attached as Exhibit A is true and correct copy of the Office of the Inspector General, Southwest Region, Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits, December 2005 (available at http://www.usda.gov/oig/webdocs/50601-08-TE.pdf, last visited March 1, re2007.)

3. Attached as Exhibit B is a true and correct copy of "Judge rejects federal OK of modified crop," The Oregonian, February 15, 2007.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 2, 2007, in San Francisco, California.

/s
William B. Rostov

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF BLAINE
vs.	) SCHMALTZ IN SUPPORT OF
MIKE JOHANNS, et al.	) PLAINTIFFS PERMANENT
Defendants,	) INJUNCTION

I, Blaine Schmaltz, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am owner of Blaine's Best Seeds, Schmaltz Family Farms, producer of certified organic seed and food products, located at 6020 22nd Avenue NE, Rugby, North Dakota.

3. I prepared a Declaration in Support of Plaintiffs' Motion for Summary Judgment, and hereby incorporate that declaration herein.

4. At the time I wrote my previous declaration, I was in the business of producing organic alfalfa seed for planting, for sprouting for human consumption, and as forage used for livestock in organic dairy and beef production.

5. At the time I wrote my previous declaration, I was concerned that the deregulation and planting of genetically engineered, herbicide resistant alfalfa had

the potential to cause me to curtail my organic alfalfa business ruining over 10 years of hard work and great economic injury. And in fact, this concern has become my reality.

6. Due to the threat from Roundup Ready alfalfa contamination, I am now required to prove to my seed customers that I am genetically modified (GM) free with a zero tolerance (on certified organic) requirement.

7. I am required to test each one of my marketed lots and fields to demonstrate that I comply with the zero tolerance requirements. The testing is expensive, and I would have to pass this cost onto my customers, increasing the cost per pound of my organic alfalfa seed.

8. If I fail one of these GM tests, I would automatically lose organic certification on those fields for a minimum of three years along with being required to destroy my crop and losing all income and expenses associated with that field.

9. In order to grow certified organic alfalfa, I must obtain seed from a seed supplier who can prove genetic purity to the zero tolerance standard. I have attempted to obtain alfalfa seed that has zero genetic contamination from breeder direct seed. Breeder seed is grown in the same areas where field tests have been conducted for Roundup Ready alfalfa. Because of the nature of alfalfa and its easy cross-pollination, it is very risky, and nearly impossible to obtain organic alfalfa seed that meets the zero tolerance standards.

10. As a grower of organic alfalfa seed, I would be liable for damages if my "organic" seed contaminated an organic farmer's fields. Thus, I have attempted to obtain insurance or reinsurance for this type of liability

and absolutely no insurance company will cover the risk of biological contamination from genetically engineered seed, or the risk of losing my organic certification and crop loss income.

11. Due to these circumstances, since the release of Roundup Ready alfalfa, I have been forced to completely abandon producing organic alfalfa seed for seed resale and food sprouting markets. My farm and business will now have to change our operations to replace my lost business, which we have worked for ten years to develop and trust.

12. My choice of freedom as a farmer is begin taken away and causing harm to future generations to come.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 1, 2007, in Rugby, ND.

/s/
Blaine Schmaltz

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, et al. Defendants.	No. C06-01075 CRB DECLARATION OF MARC ASUMENDI IN SUPPORT OF PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION, FINAL RELIEF, AND ENTRY OF JUDGMENT

I, Marc Asumendi, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am President of JC Watson Company, located in the Treasure Valley of Idaho, considered to be the premier alfalfa growing region in the nation.

3. We fear that if Roundup Ready is allowed to continue prior to APHIS completing its environmental review, and finding ways to prevent the biological contamination of our non genetically modified organism ("GMO") alfalfa, we will not have the choice of growing a conventional non-GMO alfalfa variety.

4. We believe that if Roundup Ready alfalfa is planted commercially this year, all existing US alfalfa seed production will be contaminated with some detectable level of the roundup gene within 2¬3 years

5. This will eliminate my ability to market my seed internationally and domestically

6. Our company currently grows 645 acres of alfalfa seed of non Roundup ready alfalfa varieties. Alfalfa seed currently costs $1.50 per pound. The average yield for our fields is approximately 1,000 pounds per acre. Thus, the annual value of our non-GMO alfalfa is around $967,500. If our alfalfa seed is contaminated, I will lose this economic value.

7. Planting season here in Idaho begins during the month of March.

8. Roundup alfalfa seed fields are currently being planted in all the major alfalfa seed production areas with little regard to contamination to non-GMO seed production fields. Seed field isolation standards that were used prior to the deregulation of RR alfalfa do not appear to be adequate to prevent detectible cross-contamination levels from Roundup Ready alfalfa

9. As a seed grower we have heard reports of several seed fields that have been contaminated even though the established seed certification guidelines were followed. We have also heard that several major seed companies have had Roundup GMO contamination issues on their early generation breeding lines making them unusable as conventional non-GMO alfalfas

10. If we do not do something soon, we fear we will be past the point of no return and US production of non-GMO alfalfa varieties will no longer be possible

11. We currently have to conduct lab tests on the seed of all our alfalfa seed production fields to monitor

if they have been contaminated by Pollen from a Roundup Ready alfalfa seed or hay field. This testing is all done at our expense. If my fields are contaminated, by no fault of our own, we will have no recourse

12. I believe that Roundup Ready alfalfa seed sales should be stopped now to prevent further contamination by GMO Roundup alfalfa. This would give the USDA some time to reexamine Roundup Ready alfalfa and take a closer look at the potential problems. Do we really want to move forward and potentially eliminate all non-GMO alfalfa varieties? From our viewpoint, this is the course we are on, unless immediate measures are taken.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 1, 2007, in Parma, ID.

/s/

Marc Asumendi

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, et al. Defendants.	No. C-06-01075 CRB DECLARATION OF VINCE HOLTZ IN SUPPORT OF PLAINTIFFS' MOTION FOR PERMANENT INJUNCTION, FINAL RELIEF, AND ENTRY OF JUDGMENT

I, Vince Holtz, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am owner of Vince Holtz Farms and Vince Holtz Seed, LLC, located at 18567 Locust Lane, Caldwel, Idaho 83607.

3. I am a 25 year producer of alfalfa seed, as well as a processor and marketer of non GMO ("genetically modified organism") types of alfalfa seed.

4. My business involves approximately 1.5 million pounds of non GMO alfalfa seed per year, and my markets are to customers who demand non GMO alfalfa seed for their needs.

5. I am very concerned about the release of GMO alfalfa seed in the production chain. I have been spending quite a bit of time trying to protect my farmland, machinery, facilities etc. from GMO contamination; time which would be better spent servicing my customers. Contamination of my alfalfa crop will eventually happen if GMO production and distribution is not stopped immediately.

6. I do not feel that currently I can be given a guarantee that GMO alfalfa seed will not contaminate non GMO alfalfa seed; as a matter of fact I cannot see how it will NOT contaminate due to the nature of invasive genes and pollen flow, as well as animal dispersal and transportation actives.

7. The farming season is about to begin, and planting will soon be underway. Our planting season can begin as early as two weeks from now, depending on the weather, and will continue through late April. There is also a fall planting in August that continues through September. I am not comfortable with planting seed, knowing that GMO seed will be planted as near as 3 miles from my farms.

8. I am also concerned that nationwide, the dealers who will be selling GMO seed will intensify the coverage. For instance if there are 5 million pounds of GMO alfalfa seed bagged, palletized and ready to be sold and planted; that would be another 250,000 acres planted, and the cycle goes on...more bees, more transportation, more animal consumption... more spreading of GMO contamination throughout the country. Soon, farmers and the general public will have no choice but to use GMO alfalfa seed, as it will cross contaminate very quickly.

9. The decision to end the use of GMO alfalfa seed is imperative now, as even now the costs involved to companies and growers is great, it will only be massively greater in the future. What then do we do, when all seed is genetically altered by continued contamination, and not only do we choose not to use it, but may be held liable for its' use? If all choices have been narrowed to one choice, what choice does one have?

10. If contamination of my farms, processing facility and distribution chain occurs, and I think it is inevitable if planting is allowed this year, I will lose my markets and business for me will cease to exist. If I am unable to supply a non GMO alfalfa seed to my customers, the economic impact to me will be as much as $700,000.00 per year. This does not include the impact it will have on my employees, suppliers etc.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 1, 2007, in Caldwell, ID.

/s/

Vince Holtz

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.	) Case No. C06-1075 CRB
Plaintiffs,	) DECLARATION OF MAURY JOHNSON
vs.	) IN SUPPORT OF PLAINTIFFS'
MIKE JOHANNS, et al.	) MOTION FOR PERMANENT
Defendants.	) INJUNCTION, FINAL RELIEF, AND ENTRY OF JUDGMENT

I, Maury Johnson, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am co-owner of Blue River Organic Seed, the largest supplier of organically grown field crop seed in the United States. Blue River Organic Seed grows and distributes corn, soy, alfalfa and other seed crops throughout the United States.

3. Blue River Organic Seed Co. is located at 27087 Timber Road, Kelley, IA 50134.

4. I have 25 years of experience in the seed business. I have been growing and selling organic seed since 1999.

5. The demand for organically grown alfalfa seed is growing rapidly. Agricultural practices are rapidly changing. In particular, organic livestock production is growing as the demand for organic cheese, milk, beef, and swine increases. Organic alfalfa is a key component of the forages system used to raise organic livestock.

6. We at Blue River Organic Seed focus on developing and selling high quality varieties of seed that have unique agronomic qualities resulting in better hardiness, disease resistance, and therefore better yields. We are especially concerned about growing and selling organic seed that is pure, meaning free from even traces of contamination from genetically engineered varieties.

7. Contamination in the fields of non-genetically engineered alfalfa with Roundup Ready alfalfa is inevitable, even where rules are in place to prevent contamination. For example, even if a farmer intends to harvest all of its alfalfa before it goes to seed, invariably the tractors miss some plants at the edge of the fields. These plants unintentionally go to seed. The pollen and seed then escapes into the general environment.

8. Contamination of non-genetically engineered alfalfa seed with Roundup Ready alfalfa seed is also inevitable. When alfalfa seed is harvested, it goes to a conditioning plant for cleaning and packaging. The same conditioning plants treat both non-genetically engineered alfalfa seed and Roundup Ready alfalfa seed. Conditioning plant operators sometimes make mistakes and mix seed by accident. Non-genetically engineered alfalfa seed and Roundup Ready alfalfa seed will from time to time accidentally be mixed

during conditioning. This has happened with genetically engineered corn and soy, and will eventually occur with alfalfa.

9. I believe that the most important thing that can be done to stop the contamination from Roundup Ready alfalfa is to stop the retail sale of Roundup Ready alfalfa seed. If sales of Roundup Ready alfalfa seed are allowed this year, seed and pollen escapes will spread the Roundup Ready traits contaminating non-genetically engineered alfalfa seed. Because alfalfa is a perennial crop that can last in the field from 3 to 8 years, these escapes will continue for years to come once they are planted. In my professional opinion, widespread production and retail sale of Roundup Ready alfalfa over the next 5 years will contaminate most if not all non-genetically engineered alfalfa.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on February 28, 2007 in Kelley, Iowa.

/s/
Maury Johnson

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.	)	Case No. C06-1075 CRB
Plaintiffs	)	DECLARATION OF
vs.	)	CHEP GAUNTT IN
MIKE JOHANNS, et al.	)	SUPPORT OF
Defendants	)	PLAINTIFFS'
	)	OPPOSITION TO
	)	DEFENDANTS'
	)	MOTION TO
	)	APPROVE APHIS'
	)	PROPOSED
	)	JUDGMENT

I, Chep Gauntt, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am 58 years old. I have farmed all of my life. I am the owner of Gauntt Farms, Inc. located at 23805 S. Oak Street, Kennewick WA 99337.

3. I grow alfalfa on approximately 1500-1800 acres each year.

4. I am currently on the Board of Directors of the Washington State Hay Growers Association. I was the President of this Board for 2 years during March 2004 through March 2006.

5. I am concerned that widespread planting of Roundup Ready alfalfa, and the subsequent biological contamination that may occur, will threaten my overseas markets, particularly in Japan.

6. I export my alfalfa hay to Japanese importers, including Zen-Noh and Agrex.

7. While it is true that the Japanese Government has approved Roundup Ready alfalfa for importation, the Japanese market rejects Roundup Ready alfalfa. Japanese importers refuse to import Roundup Ready alfalfa. Within the last six weeks, I was told by a Zen-Noh alfalfa buyer that Zen-Noh will not accept Roundup Ready alfalfa or alfalfa contaminated with Roundup Ready genes.

8. Within the past 6 weeks, I have also been told by an Agrex alfalfa buyer that Agrex will not accept Roundup Ready alfalfa or alfalfa contaminated with Roundup Ready genes.

9. In order to sell my alfalfa to the largest Japanese alfalfa buyers, I test my seed to prove that my alfalfa is free from Roundup Ready genes.

10. As an alfalfa grower, and as the President of the Washington State Hay Growers Association, I have long held that Forage Genetics should forestall growing Roundup Ready alfalfa in Washington until these market questions have been resolved. For example, on August 11, 2005, I wrote a letter to Mark McCaslin, President of Forage Genetics, Intl., requesting that they do not release Roundup Ready alfalfa until they obtained written verification from our Japanese export customers that there is acceptance in their markets. A true and correct copy of my August 11, 2005 letter is attached to this declaration as Exhibit A. Forage Genetics disregarded this request, and have proceeded without obtaining any verification that Japanese markets will accept Roundup Ready alfalfa.

11. Our markets are now at risk if Roundup Ready is allowed to be planted on a broad scale in Washington due to the possibility of market rejection in Japan.

Executed on March 6, 2007 in Kennewick, WA.

_____/s/_____
Chep Gauntt

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

[1] UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

BEFORE THE HONORABLE CHARLES R. BREYER, JUDGE

GEERTSON SEED FARMS, ET AL.	)	
PLAINTIFFS,	)	
VS.	)	No. C 06-1075 CRB
JOHANNS, ET AL.	)	
DEFENDANTS.	)	

SAN FRANCISCO,
CALIFORNIA
MONDAY, MARCH 5, 2007

* * *

[10] POTENTIAL RISKS, BOTH SCIENTIFICALLY AND BIOLOGICALLY HERE, ARE QUITE DIFFERENT WHEN ONE CONSIDERS HAY GROWING WHERE THE RISK IS VIRTUALLY INFINITESIMAL OF GENE TRANSFER, THAT'S PRIMARILY WHAT IS, IF NOT EXCLUSIVELY, GOING ON NOW.

IN THE SPRING HAS BEEN REPRESENTED TO US BY FDI, AND I'M SORRY THEY'RE NOT ABLE TO JOIN US, BUT IT HAS BEEN REPRESENTED TO US THAT THEY HAVE NO CONTRACT FOR SEED GROWING THIS SPRING.

SO WHAT IS HAPPENING ACROSS THE COUNTRY RIGHT NOW IS PLANTING FORAGE OR HAY AND NOT PLANTING FOR SEED, WHICH GENERALLY WILL NOT BEGIN UNTIL THE FALL OF THIS YEAR.

FROM A TIMING PERSPECTIVE IN ORDER FOR THE FARMERS TO ADEQUATELY PREPARE AND GET THEIR SEEDS, PURCHASE THEIR SEEDS BECAUSE ALL THE SEEDS NOW ARE ALL IN CHANNELS OF TRADE FOR THE SPRING SEASON, BUT MY UNDERSTANDING IS THAT IN PREPARATION FOR THE FALL THE COURT WOULD NEED TO REACH A DECISION BY EARLY JULY.

THE COURT: WELL, I'M NOT SURE I COULDN'T REACH A DECISION WITHIN THE WEEK. I'M JUST THINKING ABOUT WHETHER—AND I CAN'T REACH A DECISION TODAY BECAUSE I HAVEN'T STUDIED THE PAPERS.

WHAT I MIGHT DO, AND I ALSO APPRECIATE YOUR OBSERVATION, THAT THE OTHER INTERVENORS MAY WANT TO WEIGH IN ON THIS, THE PROPOSED INTERVENORS.

WHAT I COULD DO IS CONTINUE A HEARING FOR LATER THIS [11] WEEK, EITHER WEDNESDAY OR THURSDAY, ALLOW THE PARTIES TO PUT IN WHATEVER DECLARATIONS THEY WANT TO CONCERNING, I THINK, THE IRREPARABLE INJURY, IRREPARABLE HARM THAT WOULD BE CAUSED BY NOT ENTERING AN INJUNCTION FORTHWITH.

AND THEN HAVE A HEARING, PERHAPS, ON THURSDAY MORNING, WHICH I WOULD INVITE YOU TO ATTEND, IF YOU WISH, MAYBE AT 10:30 ON THURSDAY IN MY COURT. MEANWHILE YOU CAN GET WHATEVER DECLARATIONS YOU NEED TO GET IN.

IS THERE ANY REASON NOT TO—LET ME TURN TO THE—I WOULD THINK THAT I CAN ALLOW IN THE INTERVENORS AT THIS POINT ANYWAY, DO THE PLAINTIFFS HAVE AN OBJECTION TO THIS INTERVENTION THAT'S MERIT BASED?

MR. GOLDEN: WE BELIEVE WE DO, YOUR HONOR.

THE COURT: I'LL LOOK AT THAT AND RULE ON THAT THURSDAY AS WELL. I HAVEN'T CONSIDERED THAT. JUST SEEMS TO ME THEY'RE AN AFFECTED PARTY THAT WOULD CERTAINLY FIT THE CRITERIA FOR INTERVENTION.

I UNDERSTAND THEY'RE COMING IN LATE IN THE PROCEEDINGS, BUT THAT'S THEIR PROBLEM NOT YOURS, ISN'T IT?

MS. SCHNEIDER: THIS IS JAN SCHNEIDER. IF I COULD SPEAK TO THAT POINT FOR JUST A MOMENT. AS I'M SURE YOUR WELL AWARE, IN THE NINTH CIRCUIT PRIVATE PARTIES ARE NOT PERMITTED TO INTERVENE AS A MATTER OF RIGHT.

THE COURT: AS A MATTER OF RIGHT, I UNDERSTAND THAT, BUT AS A MATTER OF DISCRETION THEY ARE—YOU CHOSE NOT TO. I [12] MEAN, I DIDN'T KNOW. WAS I

PRESENTED WITH A MOTION TO INTERVENE? I DON'T THINK SO.

MS. SCHNEIDER: NO, YOU ARE CORRECT, YOUR HONOR, YOU WERE NOT. ALTHOUGH, UNTIL THE COURT'S DECISION CAME DOWN ON FEBRUARY 13TH IT WAS NOT CLEAR UNTIL THAT POINT IN TIME THAT MONSANTO'S INTEREST WOULD BE SIGNIFICANTLY IMPAIRED.

THE COURT: WHY?

MS. SCHNEIDER: AS THE GOVERNMENT'S ATTORNEY POINTED OUT—

THE COURT: NO, WAIT A MINUTE, I DON'T UNDERSTAND THAT AT ALL.

MS. SCHNEIDER: THE FACT THE PLAINTIFF DID NOT MOVE OR SEEK PRELIMINARY INJUNCTIVE RELIEF.

THE COURT: I UNDERSTAND THAT. WELL, ANY RATE, LET'S NOT GET INTO THAT. I DON'T THINK THE ISSUE IS WHERE WERE WE, I THINK, THE ISSUE WHERE ARE WE, AND I WILL ALSO HEAR DISCUSSION ON THURSDAY ON THAT MATTER AS WELL.

MR. GOLDEN: WE HAVE—SINCE EVERYBODY ON THE PHONE, WE HAVEN'T TOLD ANYBODY THIS, WE DIDN'T KNOW HOW THIS CASE MANAGEMENT WILL GO OUT, WE CAN PRESENT TRO MATERIALS IF WE NEEDED TO.

THE COURT: ANY SIDE TO PRESENT WHATEVER THEY WANT ME TO CONSIDER. I MEAN, I DON'T RUN THE LITIGATION.

MR. GOLDEN: WE CAN DO A TRO RIGHT NOW ON STOPPING THE PLANTING. [13]

THE COURT: I'M NOT GOING TO DO ANYTHING ON MONDAY THAT I CAN DO ON THURSDAY. I MEAN, WAIT, I JUST THINK IN FAIRNESS TO EVERYBODY, I THINK, THE GOVERNMENT'S RIGHT YOU DIDN'T MOVE FOR INJUNCTIVE RELIEF. THAT WAS AN ISSUE, PRELIMINARY INJUNCTIVE RELIEF.

THAT WAS AN ISSUE THAT ACTUALLY, I THINK, I RAISED DURING THE COURSE OF THE HEARING AND IT WAS SAID, WELL, WE'RE NOT THAT CONCERNED BECAUSE THE PLANTING SEASON NOT GOING TO OCCUR UNTIL THIS SPRING.

I GUESS, WE'RE IN SPRING AND SO NOW WE DO HAVE SOME OF THAT, AND NOW THE CONCERN BECOMES A LIVE ONE FROM THE PLAINTIFF'S POINT OF VIEW, I APPRECIATE THAT.

BUT I'M NOT GOING TO DO SOMETHING ON MONDAY WHEN I CAN--WHEN I URGE FOR THE FIRST TIME TO DO IT THIS MONDAY WHEN I COULD ACTUALLY DO IT ON THURSDAY AND GIVE THE PARTIES A RIGHT TO COME ON IN AND TELL ME WHY IT SHOULDN'T BE DONE. AND THAT JUST SEEMS TO ME FAIR.

I THINK, THERE ARE OBVIOUS ECONOMIC INTERESTS THAT ARE GOING TO BE AFFECTED HERE. AND WHEN I DO THAT BEFORE OR RATHER BEFORE I DO IT I'D LIKE

TO GIVE PARTIES THE OPPORTUNITY TO BE HEARD, SO.

MR. GOLDEN: COULD I ASK TWO QUESTIONS?

THE COURT: LET ME TURN TO THE PLAINTIFFS NOW WANT TO ADDRESS SOME ISSUES.

MR. GOLDEN: ON THE INTERVENTION ISSUES, WOULD YOU [14] LIKE US TO RESPOND TO THEIR INTERVENTION MOTION?

THE COURT: I F YOU OBJECT. IF YOU OBJECT TO THEIR INTERVENTION, YES, OF COURSE, YOU HAVE TO RESPOND.

MR. GOLDEN: BY WEDNESDAY OR THURSDAY?

THE COURT: NO, I'M GOING TO DECIDE ON THURSDAY, I'M NOT GOING TO LET THIS GO ON. IT SEEMS TO ME THAT YOU WANT TO RESPOND YOU SHOULD RESPOND, YOU SHOULD RESPOND QUICKLY TO IT AND ALLOW THEM THE OPPORTUNITY TO UNDERSTAND YOUR ARGUMENTS AND THEN PRESENT WHATEVER REBUTTAL THEY WANT TO. THEY CAN DO SO ORALLY ON THURSDAY.

IS THAT ALL RIGHT WITH MONSANTO'S COUNSEL?

MS. SCHNEIDER: YES, YOUR HONOR.

THE COURT: AND WHEN—WOULD YOU PLEASE ADVISE THE POTENTIAL OTHER INTERVENORS OF THE COURT'S DECISION. I GUESS, I COULD SEND OUT A MINUTE ORDER OR SOMETHING, SCHEDULING ORDER ON

THIS, BUT YOU CAN ADVISE THEM AS WELL. IF THEY WANT TO APPEAR THEY CAN APPEAR THURSDAY MORNING AT 10:30.

MS. SCHNEIDER: YES.

MR. GOLDEN: TO BE CLEAR, WOULD YOU LIKE US—WOULD YOU LIKE ALL PARTIES TO SUBMIT DECLARATIONS OR SHOULD WE SUBMIT AN OPPOSITION TO—

THE COURT: TO WHAT, TO THE INTERVENTION OR INJUNCTIVE RELIEF?

MR. GOLDEN: INJUNCTIVE RELIEF.

THE COURT: HAVE YOU SUBMITTED, SINCE I HAVEN'T SEEN [15] THE PAPERS, YOU'VE SUBMITTED YOUR OWN PROPOSAL, HAVE YOU STATED WHAT YOU THINK IS WRONG WITH THE PROPOSAL?

MR. GOLDEN: NOT YET.

THE COURT: THEN YOU BETTER DO THAT. WHATEVER OBJECTIONS YOU HAVE TO THE GOVERNMENT'S PROPOSAL, THEN I THINK THAT IF THERE IS QUOTE "AN IMMEDIACY ISSUE" AND THERE SEEMS TO BE AN IMMEDIACY ISSUE WHATEVER DECLARATIONS YOU HAVE IN SUPPORT OF YOUR VIEW THAT I MUST GRANT IMMEDIATE RELIEF YOU SHOULD HAVE BY WAY OF DECLARATION.

AND THAT SHOULD ALL BE FILED BY NOON ON WEDNESDAY, SO THAT THE PARTIES HAVE AN OPPORTUNITY TO REVIEW IT. NOW, IS THE GOVERNMENT COMING OUT FOR THIS?

MR. PAGE: YOUR HONOR, GIVEN THE—I ALSO—YES, YOUR HONOR, THE QUICK ANSWER IS YES, BECAUSE I KNOW YOU MENTIONED DECLARATIONS, AGAIN, THIS IS GREG PAGE, IN OUR PROPOSED JUDGMENT SUBMITTED TO THE COURT BY US WE SUPPORTED THAT WITH A 20-PAGE DECLARATION BY DR. NEIL HOFFMAN WHOSE PRIMARILY RESPONSIBLE FOR THIS PROGRAM AND FOR DEVELOPING THE SIX MANDATORY ENVIRONMENTAL MITIGATION MEASURES THAT APHIS DECIDED TO ADOPT AFTER REVIEWING THE COURT'S DECISION.

SO IN THAT DECLARATION DR. HOFFMAN IDENTIFIES APPROXIMATELY $140 MILLION WORTH OF HARM THAT WOULD, WHAT WOULD RESULT IF THE COURT TRIED OR DEVELOPED A MECHANISM FOR RESTRICTING THE MODIFIED ALFALFA HAS BEEN PLANTED BEFORE THE JUDGMENT.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al. Plaintiffs, vs. MIKE JOHANNS, et al. Defendants.	) Case No. C06-1075 CRB)) DECLARATION OF BRENT EVANS IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO APPROVE APHIS' PROPOSED JUDGMENT)

I, Brent Evans, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am the international sales manager for Eckenberg Farms.

3. Eckenberg Farms is the largest exporter of alfalfa hay in Washington State employing nearly 100 persons and purchasing hay from hundreds of farmers in the Pacific Northwest. We buy over 150,000 tons of hay annually and export around 5,000 40-ft containers per year. On a volume basis, hay from farms in Eastern Washington is the largest export from the state.

4. Japan represents 70% of the export volume both for Eckenberg Farms and for Washington State's hay exporters as a whole, with South Korea and Taiwan consuming the rest. Approximately 40% of the income from all hay produced in the state is derived from these exports. Thousands of agricultural workers, truck drivers and laborers at the ports of Seattle and Tacoma all directly depend on these exports.

5. Monsanto's recently developed genetically modified organism (GMO) called Round Up-Ready alfalfa has raised serious concerns in our industry.

6. While the Japanese government has approved the sale of Round Up-Ready alfalfa, Japan's marketplace (importers, agricultural cooperatives and dairymen) does *NOT* want to buy Round Up-Ready alfalfa. William T. W. Woodward, Extension Faculty at Washington State University, published a paper concluding: "it is likely that Roundup Ready alfalfa will be approved [by the Japanese Government]. However, the issues are more of a concern with the customer than with the government approval. Most of the alfalfa hay customers have indicated a low tolerance for GMO's in hay products." Woodward, William T.W., "Issues with GMO Alfalfa in the Marketplace," p. 1, Washington State University. A true and correct copy of this article is attached to my declaration as exhibit A.

7. Major Japanese dairy and agricultural cooperatives such as Zenrakuren and Zennoh are requiring all US suppliers of hay and forage to certify and guarantee that we have not and will not ship any Round-up Ready alfalfa into Japan.

8. The following companies that we export alfalfa to have all indicated that they will NOT import Round-up Ready alfalfa from Eckenberg Farms or other American exporters. Indeed, some have required us to provide guarantees and certificates that we will not buy or ship it. These companies collectively easily constitute the vast majority of the alfalfa and other hays imported into Japan:

a. Abe Trading Company (a specialty import company, Chiba)
b. Fuji Corporation (a specialty import company, Tokyo)
c. Kanematsu Corporation (a large trading company, Tokyo)
d. Marubeni Corporation (importing for Zenrakuren and a large trading company, Tokyo)
e. Maruyoshi Shoten (a specialty import company, Nagoya)
f. Nishi Nihon Kawayo (a regional distributor near Kobe)
g. Prime Corporation (a specialty import company, Kobe)
h. Sekido Company (a specialty import company in Kobe and Fukuoka)
i. Sojitz Corporation (importing for Zennoh and others, a large trading company, Tokyo)
j. Sumikin Bussan (a specialty import company, Tokyo)
k. Sumitomo Corporation (a large trading company, Tokyo)

l. Toyota Tsusho (importing for Zenrakuren and others, a large trading company, Tokyo)

m. Yuasa Shoji (a specialty import company, Nagoya)

9. Given the highly charged atmosphere in Japan over the issues of Mad Cow Disease (BSE), the banning of US beef imports and other similar issues, our industry fears the possibility of a severe reaction to the introduction of Round Up-Ready alfalfa that could cripple or, in the worst case, entirely stop exports of all Washington State alfalfa to Japan.

10. The consequences of such a reaction will fall primarily on the shoulders of the Washington State hay industry and on the state's economy, not Monsanto.

11. We would welcome further research on the science and environmental safety of Round-up Ready alfalfa, if for no other reason than to give our Japanese customers time to study and perhaps accept its introduction into Japan. As things now stand, however, Round-up Ready alfalfa constitutes a real threat to our business and to thousands of jobs in Washington State.

Executed on March 6, 2007, in Mattawa, WA.

/s/

Brent Evans

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

[Logo Omitted] Washington State University

ISSUES WITH GMO ALFALFA IN THE MARKETPLACE

William T. W. Woodward[1]

A GMO (genetically modified organism) debate that has continued in the past few years on crops such as corn, cotton, canola, soybean, and wheat as well as other crops has also targeted alfalfa. With the released date of herbicide resistant alfalfa coming closer, there are concerns about the effects of a GMO on the forage export marketplace. Although export alfalfa is produced in a smaller area in the United States than wheat, the same concerns for wheat can be made for alfalfa. Many growers and exporters agree that herbicide resistant alfalfa cultivars would help ease the production of weed free hay, however, they fear that the introduction of Roundup Ready alfalfa could dramatically harm the export market. Seventy-five percent of export hay from the US goes to Japan, 16% to Korea, and 7% to Taiwan. The Pacific Rim countries import about 99% of all hay exported from the US. Therefore, they have the influence on the type of product required for their use for livestock.

Japan product approval for Foods and Food Additives Produced by Recombinant DNA Techniques

The Japanese Ministry of Health and Welfare has been assessing the safety of foods and food additives produced by recombinant DNA since 1991. Early on,

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[1] William T.W. Woodward, Extension Faculty, Washington State University, Pasco, WA 99301; Email: woodward@wsu.edu.

the safety assessment of such foods and food additives was conducted on a voluntary basis. Because foods, and food additives of this type are expected to increase, the Ministry of Health and Welfare decided to introduce mandatory requirement for safety assessment of such foods and food additives and published relevant announcements to amend existing regulations on May 1, 2000 in order to avoid the distribution of such foods and food additives that has no safety assessment. According to these announcements, any foods and food additives produced by recombinant DNA techniques that have no safety assessment shall be neither imported nor sold in Japan on and after April 1, 2001.

So far, in Japan, 59 genetic events have been evaluated based on the Guideline for safety assessment, declared by the Food Safety Investigation Council and have been confirmed individually by the Minister for Health and Welfare (MHLW). The crops involved so far are Potato, Soybean, Sugar Beet, Corn, Canola and Cotton. As of October 7, 2004, two new crops have appeared on the "list of products whose safety assessments are being examined by the MHLW" (Table 1). They include a virus resistant Papaya and three herbicide tolerant alfalfa products. The alfalfa products were Roundup Ready submitted by Monsanto Japan Ltd. and developed by Monsanto Company and Forage Genetics Inc. (USA). Because herbicide resistant crops have made up over 70% of the foods that have been evaluated and confirmed, it is likely that Roundup Ready alfalfa will be approved. However, the issues are more of a concern with the customer than with government approval. Most of the alfalfa hay

customers have indicated a low tolerance for GMO's in hay products.

Table 1: List of the products whose safety assessments are being examined by MHLW

Department of Food Safety, MHLW.

As of 7 October 2004

No.	Crop	Event	Trait	Applicant	Developer
1	Papaya	55 1	Virus resistant	Hawaii Papaya Industry Association (Mac Inc.)	Cornel University University of Hawaii The Upjohn Company USA
2	Cotton	281	Insect resistant Herbicide tolerant	Dow Chemical Japan Ltd.	Mycogen Seeds / DowAgroScience L.L.C. USA
3	Cotton	3006	Insect resistant Herbicide tolerant	Dow Chemical JapanLtd.	Mycogen Seeds / DowAgroScience L.L.C. USA
4	Cotton	Variety of 281 3006	Insect resistant Herbicide tolerant	Dow Chemical JapanLtd.	Mycogen Seeds / DowAgroScience L.L.C. USA

No.	Crop	Event	Trait	Applicant	Developer
5	Corn	B.t. Cry34/35Ab1 EventDAS-59122-7	Insect resistantHerbicide tolerant	DuPont K.K.	DowAgroSciences L.L.C. /Pioneer Hi-Bred International, Inc. (USA)
6	Alfalfa	Roundup Ready Alfalfa J101	Herbicide tolerant	Monsanto Japan Ltd.	Monsanto Company / ForageGenetics Inc. (USA)
7	Alfalfa	Roundup Ready Alfalfa J101	Herbicide tolerant	Monsanto Japan Ltd.	Monsanto Company / ForageGenetics Inc. (USA)
8	Alfalfa	Variety of Roundup ReadyAlfalfa J101 Roundup Ready Alfalfa J163	Herbicide tolerant	Monsanto Japan Ltd.	Monsanto Company / ForageGenetics Inc. (USA)

Washington Alfalfa Hay Production

According to the USDA National Agricultural Statistics Service, the value of all hay in Washington in 2004 was about $371 million while the value of alfalfa hay was about $252 million. Among agricultural commodities, hay value ranks sixth in Washington. Figure 1 shows the acreage of the four top hay producing counties in the state while figure 2 shows the alfalfa hay production for the same counties. Grant, Adams, Benton and Franklin counties have about 50% of Washington's alfalfa hay acreage while producing almost 70% of the alfalfa hay. Although Washington's alfalfa hay exports are estimated to be about 20%, hay processors estimate that 35-50% of the export alfalfa hay is produced in the Columbia Basin where the four primary counties exist.

Firgure 1: Four County Alfalfa Acreage

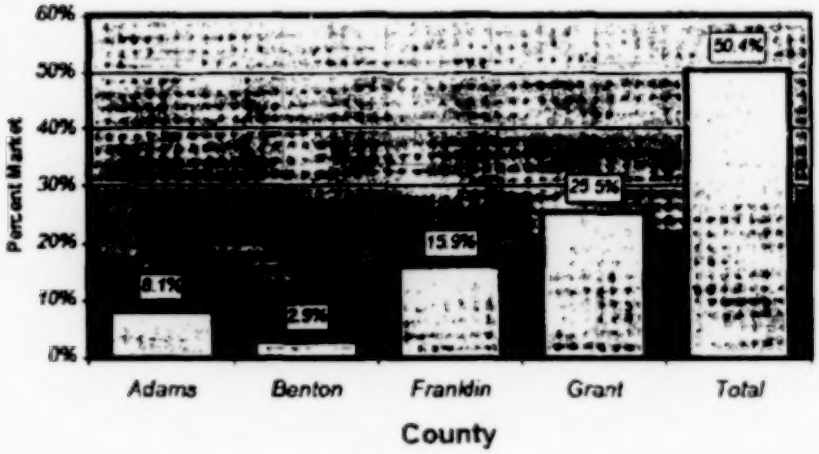

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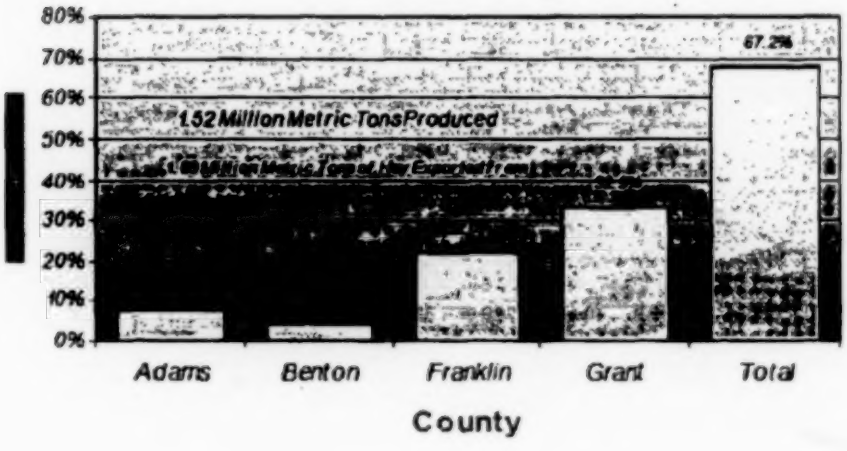
Figure 2: Four County Alfalfa Production



Forage Export Market

Exports are an important market for the PNW forage producer. The primary export products produced in Washington are double compressed bales of alfalfa and timothy as well as alfalfa cubes. The United States exported almost 3 million metric tons of forage products to the Pacific Rim in 2004. Japan's share of the market was about 74 percent with Korea's share at 19 percent. Taiwan's share was 5.7%.

While Japan's alfalfa cube imports from the US continued to decline (Figure 3), baled hay imports continue to grow, exceeding the 1.6 million metric tons mark in 2003 (Figure 4). Japans total hay imports from the US passed the 2 million metric ton mark in 2003 and will likely continue in 2004. The value of forage products as received by Japan from the US approached 480 million dollars in 2003. With 59% of the market, the value for the PNW would be about $283 million and at 30 to 50% of the PNW's share, the value for the

Columbia Basin could be estimated at 85 to 142 million dollars. In 2003, about 70 percent of forage products for Japan were shipped from the United States with about 17 percent from Canada and 11 percent from Australia (Figure 5).

Figure 3: Total US alfalfa cube imports (Japan)

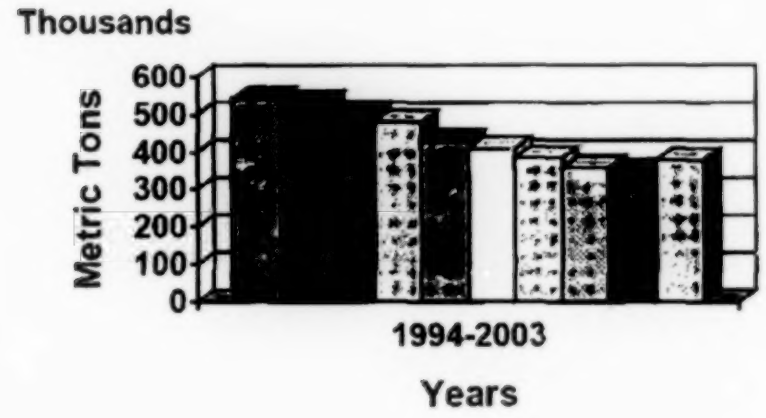


Figure 4: Total US Baled Hay Imports (Japan)

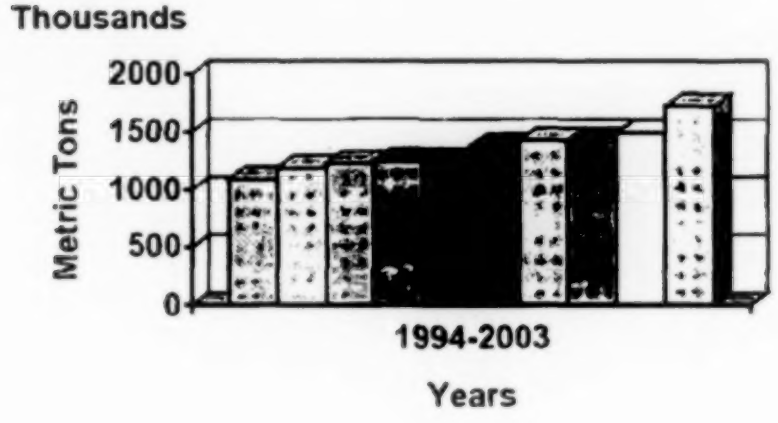
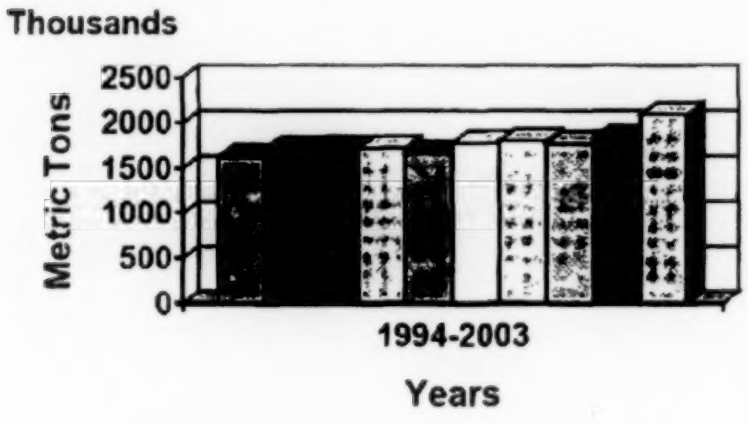


Figure 5: Total US Forage Imports (Japan)



Production Considerations

Although there could be some concerns with alfalfa used in the health and sprout market, most of the concerns involve hay headed for the export market. It is questionable if the health or sprout market knows that an alfalfa GMO will be on the market and that they might have to test for its presence.

Because 99% of hay export is from the western states, the western producers will need to know where the crop will be marketed. This will require some planning, as alfalfa is a perennial crop with stands lasting up to eight years and harvested up to five times per year in the PNW. Furthermore, the grower may export only one of those harvests in a year. It is estimated that over 80% of the growers in the Columbia Basin in Washington will export at least one of their harvests per year.

A hay processor and exporter will need to know if there is a tolerance level for the Roundup Ready gene.

Although the Japanese Government might set a tolerance level of 5% for the GMO, the customer may want as little as 0.1% tolerance. Many of the alfalfa processors and exporters have indicated that their Japanese customers have asked that there be no GMO's in their forage products.

Pollen from an adjacent field can contaminate a neighboring field as the pollinator (bees) can fly several miles. The contamination could occur in both the seed field and, to a lesser extent, in a hay field. The most likely contamination could be in purchased seed because of seed production practices that may not allow adequate isolation distances. Although contamination is expected to be low, tests may unexpectedly detect the Roundup Ready gene. It is difficult to certify that a non-GMO will not be contaminated if grown in an area where GMO alfalfa cultivars are produced.

Tests and Sampling Procedures

ELISA tests need to be developed for sensitive, quick and easy use. Each haystack could be potentially sampled and tested by the producer or the processor. A sampling procedure needs to be developed that is simple and acceptable to the export markets. The procedure will need to state sample numbers and size based on the volume of hay being tested. There will need to be instructions on using the tests for judgment of the results. The same type of procedures will need to be developed for sampling containers both before and after loading.

Liability and Contracts

Segregation of hay and seed may not be simple. Non-GMO alfalfa seed may contain low levels of GMO germplasm. Because of this, growers will want to save a sample of the seed lot and a sample of the hay lot. Contamination from pollen or volunteers from a GMO previous alfalfa crop may add to the level of detection. There are risks that could occur from planters, balers, storage areas, and trucks.

Producers will need to be careful if they are asked if the crop is not GMO. It is important that the grower watches what is signed or said. There is one exporter that stated on his contract, prior to the release of Roundup Ready alfalfa products in 2003, that no GMO is to be tolerated in purchased hay. It is expected that more hay exporters will incorporate statements such as this in their contracts. The grower will need to stick to statements such as:

- The seed company stated that the seed that I planted was not GMO.
- Care was taken to avoid contamination by equipment and storage areas.

They should not make statements such as:

- The crop has no GMO germplasm.
- No contamination has occurred from equipment or storage.
- No contamination has occurred from pollen drift.

Conclusions

Although Roundup Ready alfalfa would provide for a clean field of alfalfa, the export market should be a consideration prior to release of a cultivar. Because the western alfalfa producers are more likely to use a

herbicide for weed control than mid-western and eastern US producers, western alfalfa production would be a likely target for herbicide resistant alfalfas. However, the export hay market is important to both processors and alfalfa producers in the west where 99% of the export market occurs. There is a need to be well prepared with procedures for sampling and testing prior to Roundup Ready alfalfa cultivars appearance on the market.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

GEERTSON SEED FARMS et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	No. C-06-1075 CRB

SECOND DECLARATION OF NEIL HOFFMAN

I, Neil Hoffman, declare as follows:

I make the following representations based upon my personal knowledge and upon facts made known to me in my capacity as an official of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).

1. I serve as the Director of the Environmental Risk Analysis Division for the USDA/APHIS' Biotechnology Regulatory Services (BRS). On March 2, 2007, I provided a declaration to this Court.

2. As indicated in my first declaration, APHIS is fully committed to preparing a comprehensive environmental impact statement (EIS) prior to deciding in the future whether RRA should be unconditionally deregulated. APHIS believes that the EIS will take approximately two years to complete.

3. APHIS approves a petition for nonregulated status only after it concludes that the GE plant poses no plant pest risk. Because APHIS' determination that RRA poses no plant pest risk is still operative, it would be illogical to regulate RRA pursuant to a permitting scheme that is designed to mitigate plant pest risks. Further, the current permitting system is designed to regulate small scale field tests. Issuing permits for 220,000 acres of RRA planted for forage/hay production would be impractical. Additionally, inspecting such large acreage under permit would significantly drain APHIS resources. Therefore, prior to APHIS' completion of the EIS, APHIS proposes that RRA can be grown, harvested and used, provided it is in accordance with six stringent, science-based requirements designed to mitigate the potential environmental harms specified by this Court. This course of action is consistent with the determination that RRA is not a plant pest and would be less likely to result in foreign trade disruptions.

4. I am providing this supplementary declaration to further explain the six requirements set forth in ¶ 50 ofmy first declaration. These requirements are in addition to current Monsanto/FGI stewardship and contract requirements, and would apply to RRA planted after the date of this Court's judgment. These requirements mitigate pollen-mediated and seed-mediated gene flow and possible routes of commingling. In designing these requirements, APHIS considered that the risk of gene flow between alfalfa hayfields is negligible because market forces prompt producers to harvest prior to seed formation; typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will

produce any seeds; and fields that do not produce seeds have no potential for gene flow.

5. Furthermore, according to Daniel Putnam, Extension Agronomist at University of California, Davis *(see* Attachment #1: Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf), gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage will be negligible for several reasons. First, flowering must be simultaneous between the proximate fields, and this is unlikely because there are many different alfalfa varieties and they flower at different times. Second, sufficient pollinators must be present, they must move significantly between the two fields, and they must successfully transfer pollen from a flower in one field to a flower in another field. This series of events is unlikely because alfalfa grown for hay or forage is not stocked with bees to encourage pollination. Third, fertile embryos must mature into seeds, fall to the ground, and germinate, in spite of competition from mature alfalfa plants and the effects of autotoxicity, to contribute significantly to the dry matter of the subsequent hay crop.

6. Alfalfa is grown as a perennial crop for up to eight years. As long as seed used to plant the conventional or organic field is GE free, and the crop is managed for forage or hay, no measurable GE contamination should occur in the crop over the lifetime of that planting. The following proposed

requirements largely mitigate gene flow to conventional and organic seed production.

7. **ONE, APHIS will require isolation distances between RRA and alfalfa seed production fields to mitigate any potential pollen-mediated gene flow.**

(a) APHIS will require that pollinators shall not be added to RRA fields grown only for hay production. Without pollinators, pollen-mediated gene flow is considerably less for insect-pollinated crops compared to when the pollinators are present *(see* Attachment #2: Van Deynze, A.E. and K.J. Bradford. 2005. Pollen-mediated gene flow in California cotton depends on pollinator activity. Crop Science. 45:1565-1570).

(b) APHIS will require that growers of RRA identify and keep records of all alfalfa crops being grown within 500 feet of their fields. If alfalfa fields are located within this isolation distance, growers of RRA have specific stewardship requirements, which include preventing flowering in any RRA field within 165 feet from another alfalfa seed field and harvesting at 10% bloom any RRA field located between 165 and 500 feet from another alfalfa seed field.

(c) APHIS will require specific isolation distances, based upon the best scientific knowledge and cultural practices, for the following activities:

(1) When RRA is grown for hay production, APHIS will require that RRA be planted 165 feet from any alfalfa fields used for certified seed production. For an experiment using pollinators in a seed field and a hay field containing more blooms (i.e., 20-50%) than will be allowed by this judgment, an isolation distance of 165 feet was found to reduce pollen-mediated gene flow to under 0.2% for leaf cutter bees and 0.3% for

honey bees *(see* Attachment #3: Teuber, L.R. and S.N. Fitzpatrick. 2007. Proceedings of the Alfalfa Seed Production Symposium, March 5-6, 2007. San Joachin and Holtville, CA (in press)). Experiments with honeybees show that they fly no further than is necessary to obtain sufficient food. As the number of alfalfa blooms at a given time increases, the amount of bee movement between flowers decreases *(see* Attachment #4: Strickler, K. 1999. Impact of flower standing crop and pollinator movement on alfalfa seed yield. Population Ecology 28: 1067-1076, http://www.entsoc.org/pubs/ee/eetocs/PDF/en069901067p.pdf). As the percent bloom increases in a hay field, the hay field becomes more attractive to bees and increases the likelihood that bees will leave a seed field to forage in a hay field resulting in increased pollen-mediated gene flow. For this reason, the experiment mentioned above, using fields of 20-50% bloom overestimates the pollen-mediated gene flow expected in a field harvested prior to 10% bloom.

(2) When RRA is grown for seed production, APHIS will require that RRA be planted using the following isolation distances: 1500 feet from any alfalfa fields used for seed production, when leaf cutter bees are used to pollinate RRA; and 3 miles from any alfalfa fields used for seed production, when honey bees are used to pollinate RRA. The isolation distance of 1500 with leaf cutter bees was found to reduce pollen-mediated gene flow to under 0.1% *(see* Attachment #5: McCaslin, M. and S. Fitzpatrick 2000, 37th NAAIC proceedings, pp. 396-400, http://naaic.org/Meetings/National/2002meeting/2002Abstracts/Fitzpatrick.pdf). The isolation distance of 3 miles with regard to honey bees was found to reduce pollen-mediated gene flow to

under 0.1% *(see* Attachment #6: Teuber, L.R., et al. 2004. Gene flow in alfalfa under honeybee *(Apis mellifera)* pollination (Abstract). 39th NAAIC, http://naaic.org/Meetings/National/2004NAAIC&TC/2004abstracts/lteuber.pdf). The Association of Official Seed Certifying Agencies (AOSCA) establishes minimum standards for genetic purity, identity, and seed quality. In the United States, there are four seed classes designated: Breeder, Foundation, Registered, and Certified. Breeder seed is directly controlled by the plant breeding institution and is used to produce Foundation seed under strictly controlled conditions. Similarly, Foundation seed is used to produce registered seed. Certified seed may be produced from either Foundation or Registered seeds. For alfalfa, AOSCA standards require Foundation, Registered, and Certified seed to be produced with an isolation distance from any other alfalfa of 900, 450, and 165 feet, respectively. These distances are used to ensure 99.90, 99.75, and 99% varietal purity for the respective classes. When a grower purchases high quality varietal seed to produce a hay crop, that seed is usually Certified seed. Currently RRA seed is being produced for growers as Foundation seed. This seed is currently being produced under conditions in excess of the customary standards for genetic purity. The 1500 foot isolation distance now exceeds even that used to produce Foundation seed. In other words, the proposed isolation distance for seed production vastly exceeds the standards used for commercial seed production.

8. **TWO, APHIS will require specific harvesting conditions for RRA fields to minimize gene flow,**

especially in areas where growers are producing common alfalfa seed.

(a) APHIS will require that all RRA hay fields be harvested prior to seed set. This measure will eliminate seed-mediated gene flow from the hay fields *(see* Attachment #1). Some pollen will be produced by fields harvested at 10% bloom, but this pollen has no effect on established plants. There is no biological means by which pollen can change the genetic constitution of an established plant. Pollen can fertilize the ovules within the flowers of existing plants to yield seeds with the GE trait. However, fields that do not produce seeds have no potential for gene flow and typical mowing practices reduce the likelihood that RRA, conventional, and organic fields used for hay will produce any seeds.

(b) APHIS will require that RRA fields located within 165 feet of any alfalfa field grown for common seed production shall be harvested pre-bloom. This measure will eliminate any gene flow from RRA hayfields to common seed fields located within 165 feet.

(c) APHIS will require that RRA fields located between 165 and 500 feet from any alfalfa field grown for seed production shall be harvested at or before 10% bloom. Combined with the measures to restrict stocking hayfields with pollinators and preventing bloom within 165 feet, these measures will ensure that pollen-mediated gene flow to any common seed production is below 0.1%. Beyond 500 feet, pollen-mediated gene flow from hay fields to common seed fields is essentially zero *(see* Attachment #3).

9. **THREE, APHIS will require that farm equipment used in RRA production be properly**

cleaned after use. Some farm equipment may be shared between RRA and conventional alfalfa. The below measures minimize the spread of RRA through shared farm equipment. Alfalfa is propagated via seed; it is very difficult to propagate alfalfa from other tissues such as roots, stems, and leaves. Drying of the leaves and stems into hay kills the plant making it nonviable. RRA hay must be harvested prior to seed set making it unlikely that any viable seed will be present in the hay. The three cleaning conditions below aim to reduce the amount of seed that is caught in equipment that is shared with conventional alfalfa. Seed may be trapped in machinery such as planters or attached to the wheels of planters, harvesters, tractors or tillage equipment. As RRA must be harvested prior to seed set, it is unlikely that harvesters will be contaminated with viable seeds. However, a small amount of non-viable hay may remain in harvesters after use. To eliminate the possibility that this hay will be bundled with conventional alfalfa, harvesters will be required to be cleaned before use in conventional alfalfa fields or before it leaves the farm on which it came in contact with RRA.

(a) APHIS will require that cleaning procedures for planters, harvesters, tractors and tillage equipment be submitted to and approved by APHIS prior to implementation.

(b) APHIS will require that cleaning procedures be designed to minimize the risk of RRA seed and hay movement from the authorized production site.

(c) APHIS will require that all equipment be cleaned before it leaves the farm on which it came in contact with RRA.

10. **FOUR, APHIS will require that RRA be handled and clearly identified to minimize commingling after harvest.** APHIS will require that, immediately after harvest, RRA seed must be stored in specifically designated and clearly labeled containers until seed is transferred to FGI. Potential mishandling of RRA can be minimized by imposing measures to clearly identify RRA from conventional alfalfa. By requiring RRA to be stored in specially designated and clearly labeled containers, handlers will be less likely to confuse RRA with conventional alfalfa.

11. **FIVE, APHIS will require that RRA shall not be used for livestock grazing purposes or in a mixed grass pasture.** This condition is being imposed to restrict management options that might complicate harvest requirements. Animals left to graze a field may not uniformly eliminate flowering. Similarly, flowering in a mixed grass pasture may not be as uniform among the different species and the effect on pollinators less predictable. To reduce the potential loss of control in these management options, livestock grazing and mixed pasture use will be restricted.

12. **SIX, APHIS will require that all RRA seed producers and hay growers must be under contract with Monsanto or FGI.** These contracts must require compliance with the five preceding conditions, and these conditions must be followed for the entire life of the RRA stand. Contractual agreements have explicit obligations that must be met by the grower and Monsanto that help ensure compliance with stewardship agreements and terms of the judgment. Some of these terms facilitate co-existence. For example, Monsanto will collect and share with APHIS

all growers' GPS information. Such information will enable Monsanto, FGI and APHIS to conduct on-farm inspections to verify compliance with isolation distances and harvest requirements. Contracts require annual training for RRA seed producers. Seed production contracts also specify strict conditions for the production, handling and distribution of seed including identity preservation protocols. For example, contractor seed growers report all RRA seed production field locations to state crop improvement organizations to facilitate the industry's management of field history and isolation information. FGI grows all RRA variety seed in the United States using AOSCA and/or Organization for Economic Cooperation and Development certification standards. RRA seeds have a unique purple seed coating to distinguish them from conventional varieties and seed is processed under license only in a limited number of facilities. Seed bags are labeled "Roundup Ready® alfalfa." Seed producer contracts prohibit the sale of RRA seed for sprouting (food) use. In this way, contractual agreements facilitate compliance with the terms of the judgement.

13. Accordingly, implementation of these six requirements to RRA planted after judgement would address the potential harms identified by this Court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ___ day of March, 2007, in Riverdale, MD.

/s/ Neil Hoffman
NEIL HOFFMAN

[Division of Agriculture and Natural Resources, University of California logo omitted]

AGRICULTURAL BIOTECHNOLOGY IN CALIFORNIA SERIES PUBLICATION 8193

Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa

DANIEL H. PUTNAM, Extension Agronomist, Department of Plant Sciences, University of California, Davis

During the past decade, genetically engineered (GE) traits have been successfully commercialized in corn, cotton, canola, papaya, squash, and soybean, particularly the Roundup Ready (RR) trait that allows the herbicide glyphosate (Roundup) to be applied to kill weeds without damaging the crop. In June 2005, alfalfa *(Medicago sativa)* varieties with the RR trait were deregulated (APHIS 2005), allowing GE alfalfa varieties to be sold commercially.

In recent years, alfalfa has overtaken wheat as the third most important crop economically in the United States, exceeded only by corn and soybeans. Over 22 million acres (8.9 million ha) are harvested each year, with the largest alfalfa-producing states in the Midwest and West, particularly California, South Dakota, Wisconsin, Idaho, Minnesota, and Iowa (NASS 2005). Alfalfa is California's largest crop by area at 1.05 million acres (425,000 ha), with a value of $800 million to $1 billion. California produces more alfalfa hay than any other state.

When fully commercialized and if adapted by growers, the RR technology may cause profound

changes in the way alfalfa growers approach weed control as well as in the varieties that they grow (Van Deynze et al. 2004). However, the introduction of GE alfalfa varieties may also pose challenges to their coexistence with non-GE and organic production and marketing systems (Pridham 2004).

What are the sensitivities of alfalfa markets and consumers?

Crops with GE traits such as the RR trait or resistance to insects using *Bacillus thuringiensis* (Bt) have been used in animal feeding systems for more than a decade, and a number of studies have shown that DNA or proteins from GE crops have not been detected in milk, meat, eggs, or other products from animals that consume these crops (FASS 2005). Government agencies, using the concept of "substantial equivalence" to judge the safety of GE crops have concluded that RR alfalfa is safe to enter the U.S. animal feed market (APHIS 2005). Despite these assurances, some markets are sensitive about the presence of GE traits in alfalfa and wish to maintain alfalfa crops that do not have GE traits.

How is alfalfa used?

While precise alfalfa use patterns in the United States are not known, alfalfa hay has three major markets: dairies, beef, and horses, with minor uses for export, small ruminants (sheep and goats), processed feeds, and alfalfa pellets for pets and rabbits. The market for alfalfa seed presents separate and important issues with regards to GE traits (Mueller 2004), but its scope is smaller in acreage and more localized in western states. The potential for the RR trait to impact the

market for hay is described briefly in this publication and was considered in more detail in Putnam 2004b.

Will dairies use genetically engineered alfalfa?

Of the three major uses of alfalfa forage, dairy is clearly the driving force for U.S. alfalfa production. In California, alfalfa for dairy use may consume more than 75 percent of production, and alfalfa is often considered the staple of U.S. dairy production. Alfalfa is either raised by dairies and fed on-farm or raised independently and sold to dairies; these two systems have major differences in terms of marketability and acceptance. For on-farm use, marketing issues are confined largely to views of the dairy producer and the marketers of milk. For cash hay producers, market signals are manifest through price and willingness to buy.

It is anticipated that the dairy industry will not, with some notable exceptions, be highly sensitive to the presence of a GE trait in alfalfa. The dairy industry has already absorbed a sizable number of GE technologies that are currently components of milk production systems:

- *bovine somatotropin* (BST), a naturally occurring hormone produced via GE methods, which has been in use as a supplement for over 10 years
- Roundup Ready and Bt crops, particularly corn, soybean, canola, and cottonseed meal, all of which feature prominently in dairy feed rations
- cheese produced with rennin (chymosin) from GE bacteria

These GE traits in the dairy system have by and large not proved to be major marketing issues for dairies.

The exception is organic dairy producers, who have rejected GE crops as a component of organic certification (NOP 2005). Organic milk is a small but growing component of U.S. milk production, with the number of certified organic milk cows having increased by 277 percent from 1997 to 2001 but still constituting less than 1 percent of total U.S. milk production (Miller 2005). Organic dairy producers demand hay originating not only from non-GE alfalfa but also from fields approved for certified organic crop production.

Will horse owners use genetically engineered alfalfa?

Alfalfa and alfalfa-grass mixtures are the most important hay crop for the U.S. horse industry (Shewmaker et al. 2005). It has been estimated that there are 650,000 horses in California (Rodiek 2004). Horses are likely to be significant consumers of alfalfa, but the exact size of this market is not known. Horse owners are individual buyers, each with their own prejudices that likely influence their hay-buying decisions, a situation markedly different from the dairy and beef industries (Rodiek 2004; Lawrence 1998). As a result, it is probable that some horse owners will resist feeding RR alfalfa, but this is also not likely to be universal. Important to consider is the fact that sizable numbers of horses are sickened or die from poisonous weeds in hay each year (Pushner 2004), a quality aspect that may tip customer preference in favor of RR alfalfa over time.

Will the beef, sheep, and goat industries use genetically engineered alfalfa?

The quantity of alfalfa used in the beef industry is not known, but a larger percentage of nonalfalfa forage is

fed to beef cattle than to dairy cattle. Less than 1 percent of beef production is organic (NCBA 2005); however, for the reasons described above for dairy, it is unlikely that most beef producers will be sensitive to GE alfalfa. Food safety concerns with beef are generally more focused on specific disease issues (e.g., BSE, or mad cow disease), or on the use of antibiotics or chemicals. Organic beef requires non-GE hay. GE (or even conventional) alfalfa will not be important for grass-fed beef (another marketing category) for obvious reasons. Sheep and goat enterprises are tied to ethnic or specialty uses and may be more sensitive than beef to GE alfalfa, but the quantity of alfalfa used by this sector is very small.

What effect will genetically engineered alfalfa have on exports?

It is clear that the majority of exporters will be sensitive to the presence of GE alfalfa, at least in the initial few years of production. Across six western states, over 800,000 metric tons (881,000 t) of alfalfa, or 4.5 percent of production, is exported (table 1). Less than 1 percent of U.S. alfalfa is exported, and other classes of hay (e.g., sudangrass, timothy) now exceed exports of alfalfa. However, in some regions, such as the Imperial Valley of Southern California and in central Washington, the percentage of alfalfa grown for export is higher. In these regions, growers may export only one or two cuttings of their hay per year, but the exporter's acceptance impacts the grower's variety decision for the whole production season. Japan is the dominant recipient of U.S.-grown hay. Exporters in many cases have insisted on written contracts in which producers guarantee non-GE alfalfa. In 2005, growers who purchase the RR trait license had to restrict their

hay production to domestic use, and seed sales have been restricted in regions such as the Imperial Valley and central Washington where exports are important. Roundup Ready alfalfa hay currently may be legally exported to Canada and Mexico. Deregulation of RR alfalfa use for feed in Japan occurred in February 2006, but importers may nevertheless require imported alfalfa hay to be non-GE.

Table 1. Total production and exports of alfalfa and alfalfa mixtures, six western U.S. states (CA, ID, NV, OR, UT, WA) and U.S. total

	1997	1998	1999	2000	2001	2002	2003
Alfalfa production (metric tons)	17,585,823	17,868,807	17,678,337	17,362,701	17,475,169	18,852,902	18,478,311
Alfalfa exports (metric tons)	841,748	790,769	827,303	853,268	782,137	782,137	839,532

	1997	1998	1999	2000	2001	2002	2003
Percentage of alfalfa production exported (six states total)	4.79	4.43	4.68	4.91	4.48	4.15	4.54
Percentage of U.S. alfalfa exported	1.06	0.96	0.98	1.05	0.97	1.06	1.10

Sources: Production data is from NASS 2005; export data is from the Journal of Commerce 2004 and includes compressed hay and cubes.

How much of the alfalfa market will be sensitive to GE traits?

When considering alfalfa markets, it is important to note that alfalfa growers do not receive government subsidies, that alfalfa marketing is highly decentralized, and that its markets follow free-market conditions to a greater degree than do most agricultural commodities. Although markets reward genuinely higher-quality hay according to laboratory tests (Putnam 2004a), highly subjective and nonscientific factors frequently enter into sales. This is pertinent to the GE question. Perceptions are often more powerful than scientific arguments for buyers, and subjective factors related to forage quality and feed safety must be considered by producers who wish to sell to those markets.

It is clear from the above discussion and other analyses (Putnam 2004b) that the vast majority of alfalfa is grown for uses or markets that are not highly sensitive to the presence of GE traits. The primary markets sensitive to the GE trait in alfalfa are export markets, organic markets, and some hay grown for horses. This is likely to be less than 5 percent, and probably less than 3 percent, of annual U.S. production, but the degree of sensitivity will become more apparent as the trait is tested by growers. These sensitive markets require that GE traits successfully coexist with non-GE traits on farms and in regions where those markets are important. The presence of GE alfalfa may actually increase the demand for non-GE alfalfa or organic alfalfa, sharpening the need for product identity, trait stewardship, and coexistence on farms and in markets.

What practices can be used to allow GE and non-GE alfalfa varieties to coexist?

Coexistence between GE and non-GE alfalfa depends on understanding the biology of alfalfa production and techniques to assure market identity. The stewardship of purity of non-GE and GE traits for hay production within a region or farm depends on a range of practices, beginning with seed selection, and including the following eight points.

1. ***Select certified varieties for seed purity and quality***

The first step in stewardship of GE and non-GE alfalfa hay is the choice of high-quality seed. Only certified seed should be grown. This is likely to be the most crucial step in assuring purity in a hay product for growers selling into sensitive markets. While it is very difficult for traits (genes) to pass from one alfalfa hay field to another, some adventitious presence (AP) may occur during seed production if care is not taken to prevent it. Adventitious presence is a low level of presence of a trait (such as a GE trait) in a variety meant to be free of that trait. Crop inspection and certification services in each state have standards and recommendations to assure seed purity, which include variety identity, seed quality, and lack of contamination with weeds or foreign matter (Mueller 2004). However, testing and reporting of AP in certified seed is not required; growers who are concerned about AP of a GE trait in alfalfa seed should ask the seed company about it, and ask that it be tested or test the seed themselves. Strip tests are available for seed that can be used by growers interested in maintaining non-GE alfalfa.

2. ***Understand the potential for gene flow***

Alfalfa is cross-pollinated, requiring insect pollinators, usually honey bees (Apis *mellifera)* or leafcutter bees *(Megachile rotundata* F.) to transfer pollen from one plant to another for seed production. Cross-pollination is not required for forage production. The potential for gene flow in alfalfa grown for hay is not the same as that for alfalfa grown for seed crops due to very different production methods. The upper limits for gene flow in hay fields, however, can be estimated by looking at what happens during seed production (Mueller 2004; Rincker et al. 1988). Studies in seed fields in Idaho using leafcutter bees as pollinators showed gene flow from an RR alfalfa seed crop to a non-GE crop to be about 1.5% at 500 feet (152 m), less than 0.5% at 900 feet (274 m), and zero at 2,000 feet (610 m) (Fitzpatrick et al. 2002). Honey bees generally have longer flights than leafcutter bees; a study in California using honey bees as pollinators showed gene flow to be 1.5% at 900 feet (274 m) and below 1% at 2,500 feet (0.8 km), but sporadic gene flow (< 0.03%) could be detected up to 2.5 miles (4 km) away (Teuber et al. 2004; Van Deynze et al. 2004). These estimates were obtained under conditions that maximize pollination and seed production, conditions that are unusual in alfalfa hay fields.

3. ***Understand the limits of alfalfa gene flow from one hay field to a neighboring hay field***

Although gene transfer from one alfalfa hay field to another is theoretically possible, a range of environmental barriers make gene movement very unlikely. For AP to occur in a hay field from a neighboring GE hay field, flowering must be

simultaneous between fields (A and D, fig. 1); pollinators must be present (B); they must move significantly between fields (C); the pollen must accomplish fertilization by tripping flowers and fertilizing the ovule of the flower (E); those fertile embryos must mature into seeds (F); those seeds must be retained in the field, fall to the ground, and germinate (G); and those germinating plants must survive the competition of existing alfalfa plants and contribute significantly to the dry matter yield of the subsequent hay crop (H). The vast majority of alfalfa fields are harvested with only a small amount of flowering (0 to 25%) and zero viable seed production. Most hay harvested for the dairy market in California is harvested in the prebloom (bud) stage for high quality. The whole crop is usually removed during harvesting. A long history of failure to intentionally overseed alfalfa into existing alfalfa fields (Canevari et al. 2000) provides evidence that even in the rare case that seed were produced and left in the field, it would not be likely to germinate, grow, and compete with the existing crop and contribute significant biomass to the subsequent hay crop. Although the probability of each of these steps is not fully known, if one starts with an upper limit of 1.5% AP in seed fields at 900 feet (274 m) and applies the estimated probabilities above, the likelihood of AP occurring between hay fields becomes infinitely small, likely to be far less than 0.001% of field biomass even under high estimates of each of these probabilities. The combination of frequent harvests, lack of significant flowering, lack of significant seed production, and the highly competitive and allelopathic nature of alfalfa that prevents ready germination of alfalfa seeds in existing fields should prevent most if

not all gene transfer. However, growers should be aware that conditions that increase the potential for AP include excess flowering, high levels of pollinator activity, and conditions such as excess heat and late harvests where seed is allowed to mature, and should take steps to prevent or avoid these conditions.

[Figure 1 omitted.]

4. ***Control feral alfalfa near hay fields***

Cultivated alfalfa is not known to cross with any wild non-alfalfa *Medicago* species plants or with any weed present in the United States. It will, however, cross with feral, or wild, alfalfa *(Medicago sativa* L.) plants. Feral alfalfa is alfalfa that grows along ditch banks or roadsides that remains unharvested. It can originate from highway plantings, spilled seed, small amounts of seed from hay, or movement by birds. Since feral alfalfa is more likely to flower and set seed than alfalfa grown for hay, it may act as a bridge for pollinators between distant fields. Controlling feral alfalfa is a prudent measure to prevent movement of genes between hay fields.

5. ***Identify non-GE alfalfa hay***

The coexistence of GE and non-GE alfalfa requires a high level of awareness of crop identity for products destined for sensitive markets. This may require identification of hay lots to assure that hay lots are not mixed, a process currently practiced on commercial hay farms by growers who mark, test, and sell lots by field and farm. Organic growers already have a process by which they identify and document organic hay, so no greater paperwork burden would be generally required to deal with this situation. A "lot" for forage quality testing purposes is defined as a stack from the same

field, same cutting, weighing less than 200 tons (1,814 metric tons), with identification as to farm and field and cutting (Putnam 2002). This definition should also be used for GE as well as non-GE hay product identification.

6. ***Prevent mixing of hay lots***

Growers wishing to sell into sensitive markets must take steps to prevent the mixing of haystacks, to maintain identity, and to assure customers of that identity throughout harvesting, storage, and transport. For example, growers may use specific colors of twine to assist farm managers, farmworkers, truckers, buyers, and sellers to maintain product identity during marketing and shipping. Export and organic markets already require paperwork that identifies the lot, seller, and origin of hay, so a GE or non-GE label may be relatively simple for these marketers.

7. ***Test for GE traits in hay***

Testing procedures and test strips (available from, for example, EnviroLogix, http://www.envirlogix.com/, and Strategic Diagnostics, http://www.sdix.com/) for market identification of GE traits are routinely used for corn, soybean, and other crops, and they are now available for RR alfalfa hay. There are leaf tests for field-side analysis of fresh plant samples, mobile cored sample hay kits for testing haystacks, and commercial laboratory tests for testing of routine cored and ground hay samples. Early tests have shown that test strips detect RR hay successfully at levels of 5% or 100% and show lack of response at 0% (fig. 2). Using these tests should enable growers to confirm the absence of GE traits in their hays destined for sensitive markets and

provide assurances to buyers as to the stewardship of non-GE hay.

[Figure 2 omitted.]

8. ***Understand tolerances***

Given that the tolerance (requirements for labeling) for GE traits in food crops in Japan is 5% and 0.9% in Europe, the very small probabilities described above for AP in hay (animal feed) crops should not normally present difficulties for buyers of non-GE hay. For organic producers, the very small potential for AP should not ordinarily present significant worries for their markets, akin in many respects to the probability of influence of any nonorganic practice (such as spraying or fertilizing) from nonorganic fields that are grown in proximity to organic fields. The probability of gene flow and adventitious presence is quite low. Growers should be aware of conditions that facilitate gene movement (abundant flowering, seed production in hay crops) and should take steps to limit the potential for gene flow for markets sensitive to the presence of GE traits.

CONCLUSIONS

Roundup Ready alfalfa was deregulated in June 2005, the first GE trait to be commercialized in alfalfa. A large majority of alfalfa growers will choose or reject this technology based on need and economic factors, since the vast majority of their markets are insensitive to the presence or absence of GE alfalfa varieties. However, some growers (estimated to be 3 to 5%) producing for organic uses or export to countries or buyers concerned about GE crops must grow non-GE varieties and assure customers of the stewardship of the non-GE status of their crop. Simple methods to

assure coexistence without disruption of these markets should be effective under most conditions. The probabilities of gene transfer are estimated to be very low between alfalfa hay fields. The most important steps to assure hay trait purity are selecting non-GE varieties using certified seed from reputable companies, testing this seed for adventitious presence before planting, and maintaining product identity. Prudent steps to prevent excess flowering or seed production during hay production will be beneficial to maintain coexistence of GE and non-GE alfalfa. Steps to identify lots and maintain product identity are already in place for most commercial hay growers for organic and export markets, but these steps become more important to maintain non-GE identity for sensitive markets. Analytical test strips provide further assurance to customers of product identity. An understanding of biological and commercial factors affecting trait conservation is important in maintaining successful coexistence between GE and non-GE alfalfa production systems.

JA-462

Pollen-Mediated Gene Flow in California Cotton Depends on Pollinator Activity

Allen E. Van Deynze,* Frederick J. Sundstrom, and Kent J. Bradford

ABSTRACT

Many cotton (*Gossypium hirsutum* L.) pollination studies have been performed in the southern USA, but no data exist for California. In this study, we measured pollen-mediated gene flow (PGF) in four directions over 2 yr from herbicide-resistant source plots in upland cotton in the California cotton growing region and in a region with high pollinator activity. In addition, samples were taken from fields of conventional varieties at varying distances from fields planted with herbicide-resistant varieties to assess PGF under

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Published in Crop Sci. 45:1565-1570 (2005).

Forage & Grazing Lands

doi:10.2135/cropsci2004.0463

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Abbreviations: Bt, *Bacillus thuringiensis*; ELISA, enzyme-linked immunosorbent assay; GUS, β-glucuronidase; nptII, neomycin phospho-transferase II; PCR; polymerase chain reaction; PGF, pollen-mediated gene flow

commercial production conditions. A seedling herbicide bioassay confirmed by DNA tests was used to measure PGF. PGF was independent of direction from the source plot and declined exponentially with increasing distance from 7.65% at 0.3 m to less than 1% beyond 9 m when there was high pollinator activity. In the absence of high pollinator (honeybee, *Apis mellifera* L.) populations, PGF was less than 1% beyond 1 m. Pollen flow in commercial fields was consistent with the experimental plot data, with only 0.04% PGF detected at 1625 m (1 mile). This study confirms that PGF decreases exponentially with distance in cotton grown under California conditions and is low in the absence of pollinators, although sporadic occurrence of PGF can be detected up to 1625 m.

California produces only 4% of the cotton in the USA but exports 25% of the American crop and 5% of the seed (California Department of Agriculture, 2002; USDA, 2003). In 2003, 73% of cotton in the USA was transgenic, including almost 40% of cotton in California. In the USA, transgenic (biotech) cultivators are not separated from nonbiotech cultivars once the introduced trait has been approved by government agencies. Pollen-mediated gene flow (PGF) or other sources of adventitious presence (e.g., seed contamination or mechanical mixtures) can therefore pose problems for export of cottonseed into countries where the biotech trait may not be approved or deregulated. Cotton is generally considered to be a self-pollinating crop, but it is often cross-pollinated and the majority of cultivars are a mixture of closely related pure lines. The flowers are visited by honeybees, bumblebees (*Bombus* spp.), and melissodes

(*Melissodes* spp.) bees. Studies document that provision of honeybees can increase both seed and lint yield of cotton via improved pollination, and outcrossing rates are affected by bee activity (McGregor 1976).

Outcrossing rates reported for cotton vary depending on the location, the time period, and how measurements are taken. In the 1950s comprehensive studies using visual phenotypic traits reported 10% outcrossing in Texas to 47% in Tennessee (Simpson, 1954; Simpson and Duncan, 1956). These studies reported 28% outcrossing in Mississippi, but a mean of 2% outcrossing was reported in similar locations in Mississippi 20 yr later (Meredith and Bridge, 1973). The authors suggested the differences were due to a reduction in wooded areas and the heavy use of pesticides resulting in a decrease in bee pollinators. Also in Mississippi, Umbeck et al. (1991) measured pollen transfer to non-transgenic rows of cotton planted up to 25 m from a 4 ha field of cotton carrying the *npt*II gene. PGF dropped below 1% at distances beyond 7 m, but continued to be detectable at a distance of 25 m in solid-seeded cotton. Studies summarizing data (>15 000 samples) in Arizona, Arkansas, Mississippi, and North Carolina showed that PGF decreased exponentially with increasing distance from the pollen source and was below 1% beyond 10 m at all locations, although PGF was detected at 20 m (Kareiva et al., 1994). The same authors observed similar trends in South Africa and Argentina, although greater PGF was detected in these locations because of the presence of different pollinators. In a recent study, PGF was measured on a field scale across Arizona, Mississippi, and Texas by means of herbicide-

resistance assays and ELISAs for presence of insect-resistance genes from *Bacillus thuringiensis* (Bt) (Berkey et al., 2003). In Arizona, a 55 m nonplanted area was enough to maintain varietal purity. In Mississippi, all samples had less than 0.25% outcrossing, with distances beyond 3.7 m having no significant PGF. In Texas, PGF fell to nonsignificant levels from controls at distances greater than 14 m to the west and 25 m to the east of the pollen source. As cotton pollen is not effectively carried by wind (McGregor, 1976), it is unlikely that the directional differences were due to wind-blown pollen but could be due to the effects of wind on pollinator movement. As the advent of Bt cotton has reduced insecticide applications (Carpenter and Gianessi, 2001), pollinator activity in fields may have increased in recent years (Betz et al., 2000).

The authors are not aware of any outcrossing studies for cotton in California, where both the environment and the varieties differ from those in the southeastern USA. The California crop is approximately one-third Pima (*G. barbadense* L./*G. hirsutum*) and two-thirds Acala (*G. hirsutum*, upland) cottons, with 39% of the upland cotton being transgenic (primarily herbicide resistant) (USDA 2003). Field inspectors for the California Crop Improvement Association have observed Acala/Pima cotton hybrids in fields intended for certified seed production (hybrids are taller and slightly earlier). The foundation or registered seed from which these fields were planted was produced under isolation standards of 400 m (0.25 mile, 1320 ft) from similar types and 800 m (0.5 mile, 2640 ft) from widely different types (i.e., between Acala and Pima types). Although the frequency of

outcrossing generally meets certified seed production standards (1 in 9000 plants for foundation seed in the field, http://ccia.ucdavis.edu/ccia/cottonsts.htm; verified 17 March 2005), concern exists that contamination may be more frequent than is visibly evident. Furthermore, since morphological differences are not pronounced among the progeny of these hybrids, there is no indication of the level of contamination in the subsequent year's commercial crop. These very low levels of contamination that meet certification standards have not adversely affected crop production or market quality in the past. However, scrutiny of seed lots using sensitive assays for even rare contamination by transgenic events has raised the standards for seed genetic purity in certain markets. The goals of this research were to evaluate PGF with and without the addition of honeybees in upland cotton grown in California.

MATERIALS AND METHODS

PGF was tested in summer 2001 and 2002 in two field locations, Shafter Research & Extension Center, Shafter, CA, and Kearney Research & Extension Center, Parlier, CA, and in commercial fields in the San Joaquin Valley in 2000 through 2002. Shafter Center and the surrounding area are essentially a cotton monoculture managed conventionally for insect control. Kearney Center is a mixed cropping area including bee-pollinated crops such as orchards, melons, and alfalfa seed. We chose the Kearney location to minimize competition and migration of introduced bees to neighboring crops that may be preferred for pollen or nectar collection. Honeybees will forage the food source nearest their hive with the maximum reward and avoid collecting pollen or nectar from sources

where competition from different colonies is high (Gary et al., 1972; Visscher and Seeley, 1982). These two locations represent the commercial cotton production environment (Shafter) and a worst-case environment such as a cotton field adjacent to a bee-pollinated crop (Kearney) in California. As the majority of commercial transgenic cotton in California is Roundup Ready (Monsanto Corp., St. Louis, MO), seeds of BXN (Calgene Inc., Davis, CA; bromoxynil-resistant) cotton cv. Nova and the near-isogenic, nontransgenic cv. Maxxa provided by California Planting Cotton Seed Distributors (CPCSD) were used to minimize detection of PGF from outside the experimental plots. A herbicide bioassay (described below) on 2000 seeds from the Maxxa seedlot detected no bromoxynil-resistant seedlings. At each site, an 8- x 8-m source plot of Nova was surrounded by 60 x 60 m (0.36 ha) seeded with Maxxa in 0.76-m (30 in) spaced rows. Plots were managed through the growing season by standard methods for commercial cotton production. At Kearney, preplant herbicides Treflan (DowAgroSciences, Zionsville, IN; trifluralin; α,α,α-trifluoro-2,6-dinitro-*N*,*N*-dipropyl-*p*-toluidine) and Dual [Ciba-Geigy Corporation, Greensboro, NC; metolachlor: 2-chloro-*N*-(2-ethyl-6-methylphenyl) *N*-(2-methoxy-1-methylethyl) acetamide] were applied for weed control and cotton was planted on 1 May 2001 and 2 April 2002 with no insecticides applied throughout the growing season. At Shafter, cotton was planted on similar dates, but Temik 15G [Union Carbide Corp., Houston, TX; 2-methyl 2-(methylthio)propionaldehyde-*O*-(methylcarbomoyl)oxime] and Digon 400 EC [Wilber-Ellis, Fresno, CA; dimethoate: *O*,*O*-dimethyl S-(*N*-methylcarbamoyl) methyl phosphorodithionate] were

applied in the beginning and middle of June to control insects. The nearest BXN cotton was >1625 m (1 mile) away for all experiments except in 2002, a BXN field was located 220 m to the north of the Shafter trial. Four beehives were placed at a single conner of the experiment in Kearney at the beginning of the flowering and pollination period to ensure a high level of pollinators. No pollinators were introduced at Shafter.

Commercial fields in the San Joaquin Valley neighboring either Roundup Ready or BXN cotton were sampled at distances between 25 m and 1625 m (1 mile) from the herbicide-residetant pollen source. The fields were separated by open space. The first samples were taken at the edge of the herbicide-susceptible field and at 200, 400, 800, and 1625 m away from the pollen source field. Two fields were sampled in 2000, one in 2001 and two in 2002.

At maturity, cotton bolls were harvested from lower, middle, and upper flowers of Maxxa plants at 0.3 (adjacent plants), 1 (adjacent rows), 3, 9, and 30 m from the edge of the Nova plot in the center of the field. Samples were taken on four diagonals (SE, SW, NE, and NW) from the central plot. A sample was also taken from the central transgenic Nova plots. Each cotton boll sample (1.8 kg) was ginned and delinted by small-scale facilities at CPCSD, providing a minimum of 6000 seeds per sample. Each seed sample was bioassayed individually for bromoxynil tolerance as described in Jeanes et al. (2003). Approximately 2000 seeds from each sample were planted in flats containing potting soil (200 or 400 seeds/flat) and grown in a greenhouse in Davis, CA, with a constant temperature of 30°C and a 16-h photoperiod. A row of

25 control Nova seeds was also planted in each flat. Seedlings were allowed to grow to the cotyledon–first leaf stage. The total number of seeds germinated was recorded. Buctril 4 EC (Bayer Cropsciences, Research Triangle Part, NC; bromoxynil: 3,5-dibromo-4-hydroxy-benzonitrile) was applied at the equivalent rate of 1.1 kg a.i./ha (1.0 lb a.i./acre). A second application was sprayed 3 d later to treat any late-germinating seedlings. The number of surviving plants was scored 7 d after the initial Buctril application. PGF resulting in herbicide tolerance was calculated as:

PGF (%) – [(number of plants surviving)/
(number of plants germinated)] x 100

Samples from commercial fields adjacent to BXN cotton were bioassayed in the same way. For samples taken from fields adjacent to Roundup Ready cotton, the rolled towel bioassay was used to measure resistance of seedlings to Roundup Ultra (Savoy et al., 2001).

Leaf tissues from up to five plants per 2000 seed sample that survived the bromoxynil bioassay were collected and frozen at –80°C. Samples were ground and DNA was extracted with the Qiagen DNeasy kit (Qiagen, Valencia, CA). Seventy random seedling samples were tested by polymerase chain reaction (PCR) for the presence of the BXN transgene for 2001 field trials and 169 seedling samples were tested from the 2002 trials at Emergent Genetics (Scott, MS) using proprietary primers. Primers for an endogenous cotton gene were utilized for each sample as a positive control to ensure that DNA was of sufficient quality for PCR amplification.

Before data analysis, negative samples based on DNA tests (i.e., false positives for resistance in the bioassay) were subtracted from the number of plants surviving for those samples actually tested by PCR; values for samples not confirmed by PCR tests were not adjusted. Data were subjected to analysis of variance by Agrobase v.II (Agromomix Inc., Winnipeg, MB, Canada). To address heterogeneity of variances among locations, data were transformed by the square root of (X + 0.5) function in Agrobase v. II where X equals PGF. Regression analysis was performed on the means for each location by Microsoft Excel XP and confidence intervals were determined. Confidence intervals for PGF were calculated by equations outlined by Redmund et al. (2001):

$$\text{pUL} = [(d + 1)F1 - \alpha]/[(n - d) + (\text{d} + 1)F1 - \alpha]$$

where pUL is the upper confidence limit, d is the number of plants surviving the bioassay, n is the total number of plants. $F1 - \alpha$ is the F statistic at $P = 0.05$ with $2d$ +2 and $2n - 2d$ degrees of freedom.

RESULTS

Good plant growth and flower production were achieved at both experimental sites in the 2 yr of this study. As herbicide-susceptible Maxxa is the recurrent parent for development of herbicide-resistant Nova, their flowering was synchronous, thus ensuring ample opportunity for PGF via cross fertilization. As a result of standard agronomic practices using pesticides to control insect pests in cotton, no bees and very few insects were observed at the Shafter site in both years. In contrast, many honeybees were observed working cotton flowers at the Kearney site.

A total of 160 000 seeds (2000 seeds/sample x 4 directions x 5 distances x 2 locations x 2 yr) were sampled for herbicide resistance due to PGF. Although not all positive seedlings were assayed by DNA analyses, a minimum of five positive seedlings (out of 2000 planted/sample) were assayed for all samples when available. If there were less than five positive seedlings in a sample, all positive seedlings were subjected to DNA analysis. In 2001, of 70 DNA samples of individual seedlings (from seeds harvested from experimental plots) that survived the herbicide bioassay, 22 were negative for the presence of the transgene. In 2002, 33 of 149 seedlings from experimental plots and 16 of 20 seedlings from field samples that were tested by PCR showed negative results. This indicates that there were moderate to high rates of false positives in the bioassay tests. Values for the DNA-tested plots were corrected, but as not all samples were confirmed by PCR, our data likely overestimate the actual extent of PGF. In addition, two samples suspected of being outliers (Shafter SW 2001, 1 m and field 2002-1, 1625 m) were bioassayed a second time followed by DNA testing of surviving seedlings. Those values were adjusted in the average of the two assays after correcting for false positives based on the DNA tests.

Analysis of variance was conducted with data average over distances from the pollen source. The analysis indicates that locations were significantly different (P = 0.02) and that samples collected at different directions from the pollen source did not differ significantly (P = 0.97). This was confirmed by analyses of individual experiments (data not shown). Analysis of variance was thus conducted on data with

distance from pollen source and year as independent variables. Bartlett's test for homogeneity of variances was conducted for transformed PGF data. Although Bartlett's test indicated that variances were not homogeneous across experiments for original data, Bartlett's tests on transformed data were nonsignificant when combined over years for Kearney ($P > 0.05$) and Shafter ($P > 0.05$, data not shown). The data were thus analyzed for each location with year and distance as independent variables. Each mean for distance was based on data points collected from eight samples x 2000 seeds/sample = 16 000 seeds. Analysis of variance on transformed data indicated that PGF differed significantly with distance for Kearney ($P < 0.001$) and for Shafter ($P < 0.001$). Regression analysis was conducted for each location representing environments with and without pollinators. PGF decreased from 7.65% at 0.3 m to 0.67% at 9 m and 0.32% at 30 m at the Kearney site where honeybees were provided; a negative exponential curve explained over 99% of the variance at this site (Fig. 1). Confidence intervals indicate that at worst, 0.41% PGF is expected at 30 m with honeybees present. At Shafter, where no honeybees were provided, PGF decreased from 4.86% at 0.3 m to 0.30% at 1 m and remained at 0.03% at longer distances; the upper confidence limit was below 0.08% beyond 1 m (Fig. 1).

The results for samples taken from commercial fields neighboring either glyphosate- (Roundup) resistant or bromoxynil-resistant cotton are consistent with those from experimental plots. The values from field samples of bromoxynil-resistant cotton (2002-1) do not differ significantly from those from field samples of glyphosate resistant cotton (Fig. 2). PGF percentages

for field samples taken at approximately 30 m (average 0.34%) were slightly higher than in experimental plots at the same distance from the source (average 0.17% over both locations). The 30 m sample was taken from the edge of the field closest to the herbicide-resistant field and the fields were separated by open space instead of solid seeded cotton as it was the case for the plots. PGF was sporadic beyond 30 m, ranging from 0.01 to 0.10% at distances between 200 and 1625 m. PGF was on average below 0.1% at 400 m, the minimum distance required for isolation of foundation class seed fields in the USA (California Crop Improvement, 2005, http://ccia.ucdavis.edu/CCIA/standards_frame.htm). An average PGF of 0.04% was detected at 1625 m on the basis of samples taken from three different sites in 3 yr. Because of the low and sporadic nature of PGF beyond 30 m, only 24% of the variation could be explained with the best fit curve compared to 99% at distances below 30 m with honeybee pollinators (Fig. 1 and 2).

DISCUSSION

Herbicide resistance provides a simple and effective means to monitor PGF, as any resistant seedlings growing from seeds harvested from herbicide-susceptible trap plants are presumed to result from pollen transfer (Marshall et al., 2001; Messeguer et al., 2001; Berkey et al., 2003). Herbicide resistance allows large numbers of seedlings to be screened, permitting detection of relatively rare pollen flow events. However, our data highlight the importance of confirming results of the bioassay for bromoxynil resistance with a secondary protein or DNA test. Bromoxynil is a contact herbicide that is most effective in sunlight when plants are vigorously growing (Jeanes

et al., 2003). DNA tests were done on a maximum of five individual plants per 2000 seed sample. A disproportionate number of negative seedling samples

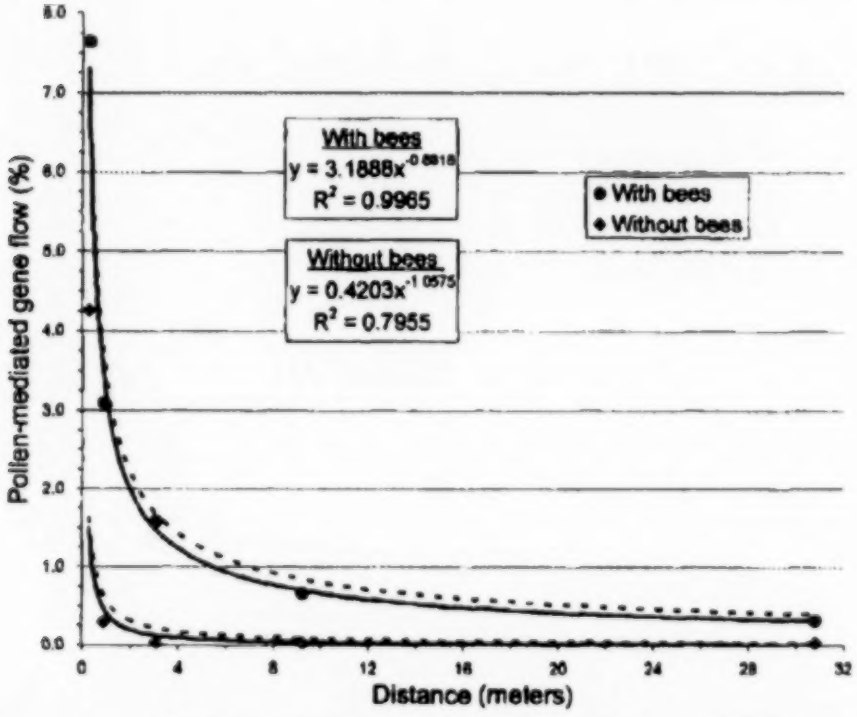

Fig. 1. Pollen-mediated gene flow (PGF) in California with (Kearney, circles) and without (Shafter, diamonds) the addition of honeybees. Each data point represents PGF detected from 16 000 seeds sampled in four directions from a source plot in two growing seasons. Solid lines represent the best fit curve for the two datasets. Broken lines represent 95% upper confidence limit.

(13/35) in DNA tests is 2002 were from the Kearney NE samples and the 16 negative field seedling samples were also from a single site. All these samples were assayed simultaneously in December 2002–January

2003 when there was a period of cloudiness causing uneven growth and poor expression of symptoms, resulting in false positives (survival of susceptible seedlings) in the bioassay. These results were obtained even under supplemental lighting conditions (see Materials and Methods). On the other hand, no mortality was observed in the control bromoxynil-resistant plants in each flat, suggesting that the false negatives (i.e., death of resistant seedlings due to other causes) were very low. Overall, we are confident in the trends in our data, but actual percentages of PGF are likely overestimated because of the occurrence of false positives in the bioassays.

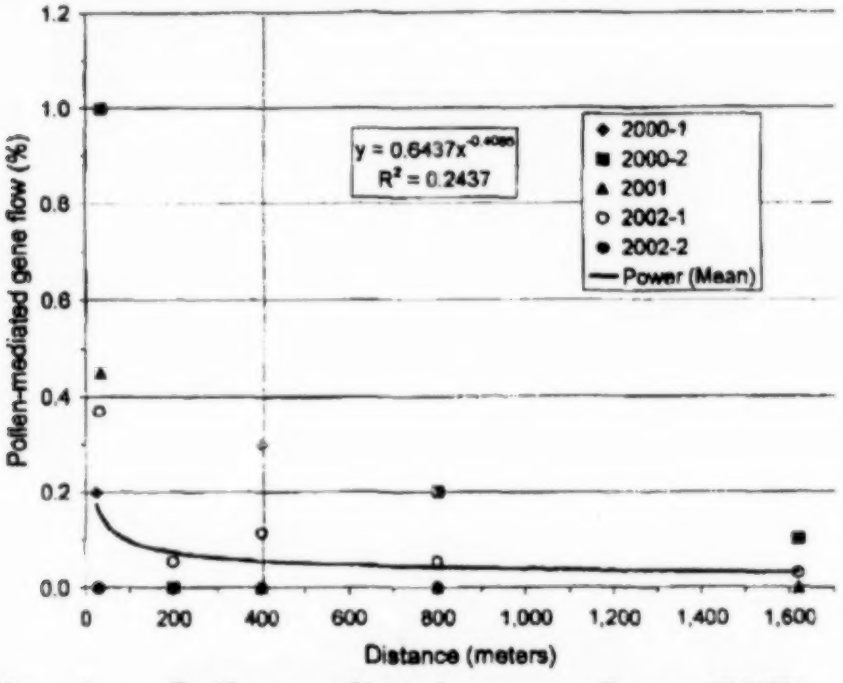

Fig. 2. Pollen-mediated gene flow (PGF) in California collected from neighboring fields separated by open space in five different locations in three years. PGF was calculated on the basis of samples (2000 seeds each) collected at the closest

edge of solid-seeded commercial fields (25–34 m), 200, 400, 800, and 1625 m from herbicide-resistant (BXN or Roundup Ready) cotton. Solid line is the best-fit regression curve. Broken vertical line represents the current isolation distance for foundation seed of 400 m.

Using bromoxynil in the current study, 25% (55/219) of seedlings were escapes on the basis of DNA analysis. Messeguer et al. (2004) tested gene flow between cultivated and wild rice (*Oryza rufipogon* Griff.) using glufosinate ammonium herbicide resistance as a marker for PGF. Of 71 seedlings surviving the herbicide bioassay, 25 (30%) proved to be escapes after testing using a GUS (β-glucuronidase) assay and progeny analysis. In contrast, in a pollen flow study in alfalfa, we tested 2200 seedlings that survived a bioassay with glyphosate (Roundup). There were no escapes in this bioassay (Teuber et al., 2004). On the basis of DNA analysis, no escapes were observed by Umbeck et al. (1991) for 68 seedlings surviving a kanamycin bioassay. These results emphasize the need to evaluate and confirm bioassay results for gene flow studies.

PGF in cotton is affected by the presence of honeybee pollinators (Fig. 1). With the low pollinator activity at Shafter (characteristic of cotton-growing regions of California), PGF dropped from 4% at 0.3 m (neighboring plants) to 0.3% at 1 m and remained sporadic and below 0.1% up to 30 m in experimental plots. Samples from commercial fields showed that up to 1% PGF can be detected at the edge of neighboring fields (approximately 30 m from source) when open space separates the fields, but this quickly decreases within 200 m to less than 0.1% on average, with 0.04%

PGF detected at 1625 m (1 mile) within a field. Providing bees (four hives adjacent to a 0.36 ha plot) increased the percentage and distance of outcrossing, but PGF was still < 1% beyond 9 m from the source plot (Fig. 1). PGF declined exponentially with distance from the source plot, as was found by Kareiva et al. (1994) across the USA, as well as in Argentina and in South Africa. Kareiva et al. (1994) suggested that the differences in PGF among locations in the USA, Argentina, and South Africa were due to the presence of different natural pollinators. This is consistent with data gathered over time in Mississippi, where PGF has shown a gradual decline from 28 to 1% between 1954 and 1991 (Simpson, 1954; Umbeck et al., 1991), likely as a result of a decrease in natural pollinators because of deforestation and use of pesticides. Our data are also consistent with recent studies showing 0% PGF in neighboring fields when separated by open space of 17 m in Arizona, less than 0.22% at distances beyond 1 m in Mississippi, and less than 1% beyond 10 m in Texas (Berkey et al., 2003).

Many factors such as flower structure, pollen attributes, self-incompatibility, wind, and kind and number of pollinators may affect PGF in plants. Cotton blooms from bottom to top with a cream-colored flower opening in the morning shortly after dawn, turning pink in the afternoon and closing at night, never to reopen. The flowers are self-fertile and pollen grains are large and coated with a viscous material that causes them to adhere to each other and prevents them from being carried by wind (McGregor, 1976). Chaney (1985) studied honeybee activity and their relative preference to visit cotton, alfalfa (*Medicago sativa* L.), corn (*Zea mays* L.), safflower (*Carthamus tinctorius*

L.), bindweed (*Convolvulus arvensis* L.), and spikeweed [*Hemizonia pungens* (Hook. & Arn.) Torr. &. A. Gray] in California. He showed that even though cotton made up the majority of the crop surrounding the beehive, honeybees worked the source of food that gave the largest reward. For example, honeybees traveled 5 km for maize and 8 km for safflower to collect pollen, bypassing cotton. In fact, cotton was the least collected pollen of the six plants studied, although honeybees readily visit cotton for nectar. Vaissière and Vinson (1994) conducted a similar study in the laboratory by presenting honeybees with pollen from cotton, okra [*Abelmoschus esculentus* (L.) Moench], pumpkin (*Cucurbita pepo* L.), corn, carelessweed (*Amaranthus palmeri* S. Watson) and sunflower (*Helianthus annuus* L.), representing pollen grains that vary in shape, size and structure. As a result, there is a large difference in how they are moved from flower to flower. For example, corn has large pollen grains with a smooth surface that is carried short distances by wind. Cotton has large echinate pollen grains with long spikes that are covered in a "viscid" material. Except for okra (also in the Malvaceae), significantly less cotton pollen was collected than from other taxa, even though bees visited cotton pollen with equal frequency and duration. Honeybees took considerably longer and carried smaller cubicular loads with cotton pollen. The cubicular loads were up to 39 times less than for corn and sunflower. The authors ruled out size, repellents, and presence of pollenkitt and concluded that the length of the spines on cotton pollen grains prevent them from packing tightly, thus preventing large cubicular loads. This in turn results in little or no transfer of cotton pollen in the hives, as

was demonstrated by Loper and Degrandi-Hoffman (1994). The low reward for honeybees in collecting cotton pollen thus acts as a deterrent for collection and accounts for relatively low PGF observed for an insect-visited crop.

Our studies quantify the extent of PGF in cotton under California conditions in both the presence and absence of added pollinators. In the absence of pollinators, significant PGF was observed only at distances of less than 10 m and the majority of PGF occurred between adjacent plants. This study complements the field-scale study by Berkey et al. (2003) across the southern USA and helps define isolation standards for U.S. cottonseed production for different markets.

ACKNOWLEDGMENTS

The authors would like to acknowledge the California Crop Improvement Association and Bayer CropScience for funding this research. In-kind support is also appreciated for cotton seed and delinting by California Planting Cotton Seed Distributors and for DNA tests by Emergent Genetics. We acknowledge technical support from Ernie Roncoroni, University of California, Davis.

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JA-483

Assessment of Alfalfa Gene Flow Between Fields Planted for Hay Production and Adjacent Fields Used for Seed Production

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Keywords: alfalfa, lucerne, *Medicago sativa*, seed production, gene flow, pollen flow, hay-to seed gene flow.

The potential for gene flow between alfalfa fields is influence by whether the alfalfa fields are grown for seed or grown to produce forage[3]. Effective pollen-mediated gene flow can occur in seed fields if physiologically mature seeds are produced on plants within the seed field (sink/recipient plants) that were pollinated by pollen that did not originate within the seed field (source). Forage ("hay") alfalfa fields have optimum feed value when the plants are primarily vegetative, that is, when the canopy is pre-bud or has less than 10% of the stems with one open flower (and no seed has been set). Alfalfa fields managed to produce high quality forage will typically have no or only a few open flowers and available pollen. One would anticipate that plants in fields such as this will

[3] Putnam, D.H. 2006. Methods to Enable Coexistence of Diverse Production Systems Involving Genetically Engineered Alfalfa. Univ. of Calif. Publication #8193. http://anrcatalog.ucdavis.edu/pdf/8193.pdf

not attract large numbers of bees foraging for either nectar or pollen, and therefore will likely have a low potential to serve as a source of outside alfalfa pollen.

Effective gene flow between alfalfa production fields can be grouped into three categories: Seed-to-Seed, Hay-to-Hay and Hay-to-Seed. This document summarizes available data on the potential for Hay-to-Seed type of gene flow. Two different field studies have been conducted in which effective gene flow was measured from Roundup Ready® hay fields (sources) to conventional seed fields (sinks). These studies used the Roundup Ready trait as a marker tool to easily and accurately measure pollen flow. The first study was conducted in 2000 in Washington. Alfalfa leafcutter bees (*Megachile rotundata*) were used as pollinators on the conventional germplasm seed plots and the 0.1 acre Roundup Ready alfalfa hay field was allowed to go to 50% bloom during midsummer (study and data were originally described in the 2004 Petition for the Deregulation of Roundup Ready Alfalfa[2]). Two replicate seed plots, 0.1 acre each, were planted at 150 or 300 ft isolation and the seed was evaluated for percentage containing the Roundup Ready trait.

A second, larger hay-to-seed study is currently being conducted at the University of California, Davis. This study was initiated in 2006 using honey bees (*Apis mellifera*) as pollinators on the seed plots (Figure 1). The 1.32 acre hay field (source) was planted with a Roundup Ready cultivar. Extending from the hay field in four different directions are one-third acre seed fields planted to a conventional cultivar. The central hay field was harvested on a 30 to 34 day cycle

[2] USDA Petition for Deregulation: http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf.

throughout the 2006 production season. This cutting cycle permitted the forage to reach as much as 20% bloom in each cutting cycle. The leading edge of each seed field was located at 165 feet from the Roundup Ready hay field and extended for 500 feet. Seed fields began to bloom on the 4th of June 2006. Honey bees were placed at a central location in these fields on June 22 when the seed crop was estimated to be at 80% bloom. When the bees were placed in the seed fields, the hay field was at a pre-bud developmental stage. It was harvested on June 28 and again on August 1. At the time of both hay harvests in 2006, the hay field was at about 20% bloom and the seed fields were in full bloom.

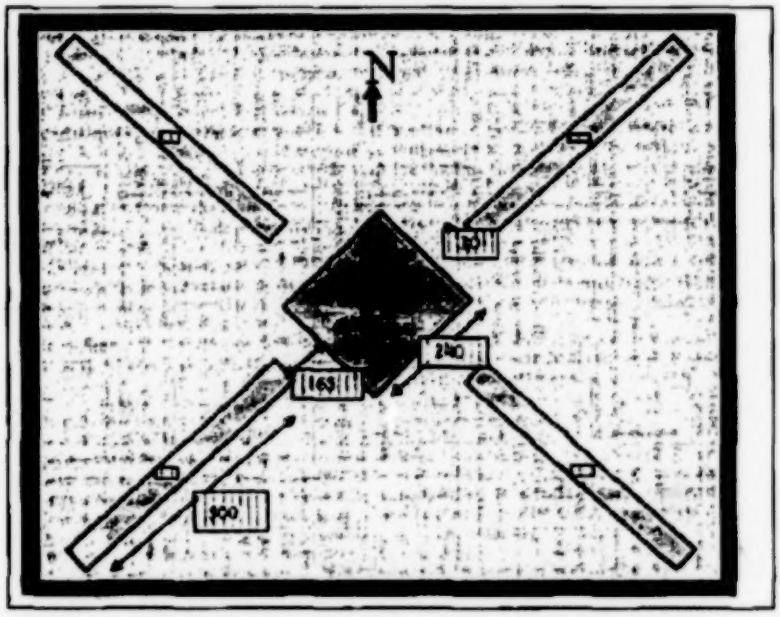


Figure 1. Field plot design for Hay-to-Seed gene flow study at the University of California, Davis. Center area is a 1.32 acre hay field planted to a Roundup Ready alfalfa cultivar (240 x 240 ft) and each of the radinga

arms are 0.33 acre seed fileds (30 x 500 ft) planted to conventional alfalfa (combined area 1.32 acres wherein honey bee hives were placed at the center points.

The choice of 165 ft between the hay and seed field in the California study was based on the minimal isolation standard required between dissimilar cultivars under the California seed certification standards. Although the California study examined gene flow to a greater distance from the source than the earlier leafcutter study, first year results from the Honey bee study were similar to the results from the earlier leafcutter bee study between 165 and 300 feet from the marker source. Under these conditions, gene flow into the seed field was very low (0.2%) at 150 and 300 ft and, it was rarely detected (0.00 to 0.05%) at distances greater than 350 ft from the source (Table 1).

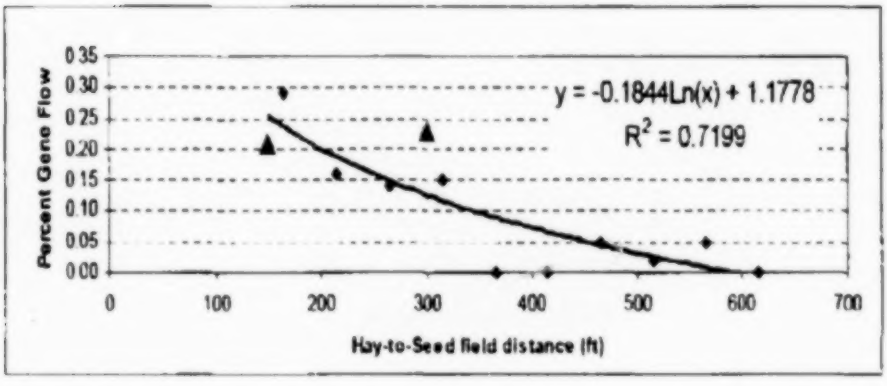
Certified alfalfa seed must be produced using production methods and isolation defined and inspected by state seed certification organization. And, Organic seed production must be managed according to a plan approved by an accredited organic certifier. Non-certified seed is not officially regulated. Seed producers and regulators recognize that genetic purity of the harvested seed crop is related to physical isolation between the seed field and outside sources of pollen. These results are consistent with existing standards for certified seed production. Additional assurances can be achieved by entering into an Identity Preserved (IP) agreement with a seed certification association that is a member of the Association of Official Seed Certifying Agencies (AOSCA).

Table 1. Observed gene flow from 50% and 20% hay production plots growing in close proximity to replicated alfalfa seed field plots in 2000 and 2006. These trials simulated delayed harvest hay fields growing near and beyond the AOSCA certified seed field isolation distance (i.e., 165 ft). In 2000, replicated seed plots in Washington were grown near hay allowed to mature extensively to 50% flower (5X the optimum hay cut stage), stocked with leafcutter bees and separated by 150 or 300 ft isolation from the Roundup Ready® hay field plot. In 2006, replicated seed field plots at the University of California were grown near to hay allowed to mature twice to 20% flower (2X the optimum hay cut stage), stocked with honeybees and separated by 165 to 615 ft isolation from the Roundup Ready hay field plot.

Isolation Distance from Hay Source	2002 leafcutter bees[1] (Hay cut at 50% bloom)	2006 honey bees (Hay cut @ 20% bloom)
----feet ---	---------- percentage gene flow ----------	
150	0.21	--
165		0.29
215		0.16
265		0.14

Isolation Distance from Hay Source	2002 leafcutter bees[1] (Hay cut at 50% bloom)	2006 honey bees (Hay cut @ 20% bloom)
300	0.23	--
315		0.15
365		0.00
415		0.00
465		0.05
515		0.02
565		0.05
615		0.00

Figure 1. Observed gene flow (Y %) from hay field plots growing near replicated alfalfa seed field plots in 2000 (▲) and 2006 (◆). These trials simulated delayed harvest of hay fields growing near and beyond the AOSCA certified seed field isolation standard (i.e., 165 ft). In 2000, replicated hay plots in Washington were allowed to mature to 50% flower (5X the optimum hay cut stage), seed field plots were stocked with leafcutter bees and separated by 150 or 300 ft from the Roundup Ready® hay field plot[2]. In 2006, replicated seed field plots at the University of California were allowed to mature to 20% flower (2X the optimum hay cut stage), seed field plots were stocked with honeybees and separated by 165 to 615 ft from the Roundup Ready hay field plot.



SUMMARY

The amount of hay field flowering that was allowed in these research trials, especially in the Washington trial, is greater than would usually be practiced by forage producers. Growers will usually manage for optimum forage quality which will minimize the

number of open flowers on the standing hay. These studies indicate that when alfalfa seed growers observe reasonable isolation distances between their alfalfa seed fields and forage fields (e.g., seed growers who implement the recognized AOSCA certified seed minimum isolation standard of 165 feet or greater) they may minimize or avoid the risk of adventitious presence (AP) of the Roundup Ready or other foreign traits in their seed crop. Additionally identity preserved (IP) programs are a service offered by certification agencies that can be employed by those seed producers interested in following more stringent practices.

JA-491

Impact of Flower Standing Crop and Pollinator Movement on Alfalfa Seed Yield

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Environ. Entomol. 28(6): 1067-1076 (1999)

ABSTRACT For agricultural crops that depend on pollination, the impact of flower abundance and pollinator movement on seed or fruit yield is of economic importance, and may have implications for crop and pollinator management. Using alfalfa, *Medicago sativa* L. (Leguminosae), I tested the hypothesis that seed set is lower when standing crop of open flowers is high than when standing crop is low. This could occur if pollinators move more among flowers on the same plant, causing self-pollination, when flowers are abundant. In a greenhouse experiment I compared seed set for 3 simulated pollinator movement patterns between flowers on the same versus different plants, under the 2 standing crop regimes generated by varying the number of flowers hand-pollinated each day. Treatments maximized, minimized, and were intermediate in movement between flowers on different plants. Significantly more seeds were produced per pod when flower standing crop was low than when standing crop was high. I hypothesized that movement pattern would have a greater effect when standing crop was high rather than low. Despite a trend in the expected direction, this interaction was not significant. Field observations of within versus between plant movement

of the pollinator, *Megachile rotundata* (F.) (Megachilidae), indicated that the bees visit more flowers per raceme when standing crop is high than when standing crop is low. In a series of hand pollination among flowers on the same plant, seeds per pollination decreased between the 1st flowers pollinated and later flowers pollinated in succession. Alfalfa may yield less seed when flowers are abundant, suggesting that early introduction of bees into alfalfa seed fields is desirable to maintain a low flower standing crop.

KEY WORDS *Medicago sativa*, *Megachile rotundata*, pollination ecology, alfalfa, seed production, foraging behavior

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IN THE MUTUALISTIC interaction between flowering plants and their animal pollinators, plant characteristics such as density of open flowers, and pollen and nectar resources, can impact pollinator behavior. Pollinator behavior, in turn, can impact the movement of pollen within and between plants and thus the amount of outcrossing and inbreeding in plant populations. Outcrossing often increases, and inbreeding often reduces plant fitness (Darwin 1876) in both agricultural crops (McGregor 1976, Frankel and Galun 1977, Erickson 1983, Free 1993) and in natural populations (Charlesworth and Charlesworth 1987, Sakai et al. 1989, Rathcke and Real 1993). Because of these plant-pollinator interactions, levels of outbreeding may vary over time in a given plant population. For example, during peak bloom when flower standing crop (the number and density of open flowers and level of resources that they contain) is high, pollinators may move more among flowers on the

same plant, causing more selfing, than early or late in the blooming season when flowers are sparse. Conversely, the more pollinators, the more competition there is for floral resources. Competition may reduce pollen and nectar levels in flowers, increasing pollinator movement between plants.

For agricultural crops that depend on pollination, the impact of pollinator movement and flower standing crop on seed or fruit yield is of economic importance, and it may have implications for crop and pollinator management. Alfalfa, *Medicago sativa* L., (Leguminosae), grown for seed (principally for the forage industry) requires a pollinator to trip the flower and thus transfer pollen to the stigma. Ovule fertilization, seed set and seed viability are lower for self-pollinated flowers than for cross-pollinated flowers (Cooper and Brink 1940, Tysdal et al. 1942, Free 1993), although individual plants vary considerably in their ability to develop self-fertilized seed (Cooper and Brink 1940, Tysdal et al. 1942, Sayers and Murphy 1966).

In alfalfa pollination, a single flower visit that results in tripping (Free 1993) provides the flower with all the pollen that it will receive for pollination, and exposes all of the pollen and nectar resources that a bee can expect to harvest at the flower. There is no gradual maturing of anthers bringing in pollinators to a flower several times over the bloom of the flower. The change in appearance of a tripped flower is obvious to the pollinators, and they rarely revisit a flower once tripped. Flowers wilt within ≈4 h after they are tripped (Vansell and Todd 1946; unpublished data), whereas flowers remain open 5-7 d if not pollinated (Carlson 1928, Free 1993). The seasonal pattern of availability of open, unpollinated flowers is

characterized by an initial burst of bloom, followed by an exponential decline in numbers of racemes with open flowers (Strickler and Freitas 1999). A more rapid decline in numbers of open flowers per raceme is attributed to steady pollination causing a decrease in the longevity of open flowers (Strickler and Freitas 1999). Nectar availability also declines over the season (Strickler and Freitas 1999).

In the northwestern United States, alfalfa has been pollinated predominantly by the introduced alfalfa leafcutting bee, *Megachile rotundata* (F.) (Megachilidae), for >30 yr (Bohart 1972, Hobbs 1972, Stephen 1981, Richards 1984). Unlike honey bees, which avoid the tripping mechanism of alfalfa flowers and learn to remove nectar from the side without effecting pollination, *M. rotundata* females visit most alfalfa flowers for pollen, food for the larvae, and thus trip most of the flowers that they visit. Seed yields increased dramatically in the 1950s and 1960s when growers began to manage *M. rotundata* (Olmstead and Wooten 1987).

In alfalfa seed production, both the plant and its pollinators can be manipulated to create conditions favorable for pollination, such as synchronizing peak bloom with maximum bee activity. For example, clipping plants or cultivating in early spring will delay bloom for several weeks, increasing the probability that bloom will occur during warm weather when bees forage. The timing of *M. rotundata* emergence in spring can be managed by incubating prepupae at 30°C 3-4 wk before the start of pollination (Baird and Bitner 1981, Stephen 1981, Murrell 1994). Incubation temperature can be further manipulated to slow emergene by ≈1 wk if weather conditions are

unsuitable for pollination. Growers release bees into their fields anytime between ≈10% and near peak bloom, depending on personal preference, timeliness of bee incubation, weather, and field conditions.

Does the timing of bee release relative to bloom phenology affect seed yields? For a given bee population, the more flowers that are in bloom, the more bees may move among flowers on the same plant rather than between plants, increasing geitonogamy (i.e., pollination by pollen from other flowers on the same plant) (Hessing 1988; Dudash 1991; de Jong et al. 1992, 1993; Cruzan et al. 1994; Harder and Barrett 1995; Back et al. 1996). In alfalfa, some of the pollen that lands on a stigma may be from the newly tripped anthers of the same flower, but if outcrossing also occurs, the self-pollen will fertilize few ovules (Pankiw and Boulton 1965, Sayers and Murphy 1966). Pollen deposited by the pollinator will vary in the proportion that comes from the same plant versus other plants, depending on the pollinator's recent foraging and grooming history. The more pollen from other plants, the greater the number of seeds produced, other factors being equal. The timing of bee release relative to percent bloom could affect the movement of bees between plants, the amount of outcrossing pollen available on the bee, and thus seed yields.

In this study I used hand pollinations of alfalfa in a greenhouse to examine the effects of simulated bee movement patterns within and between plants on seeds per pod. I hypothesized that fewer seeds per pod would result with more movement among flowers on the same plant, and movement within a plant would be greater when flower standing crop was high than when standing crop was low. I also hypothesized that

standing crop would have less effect on seeds per pod when movement was mostly between flowers on different plants.

I observed *M. rotundata* movement in alfalfa fields to determine how frequently they moved within and between plants early in the season when flower standing crop was high versus late in the season when standing crop was low. In both the greenhouse and field, I assessed pollen carryover by measuring the change in seeds per pod for a sequence of flowers hand-pollinated on the same plant. The results demonstrate the potential effects of pollinator movement on seed yield in alfalfa. Although some of the data are based on observations of *M. rotundata*, my intent was not to accurately imitate one specific bee species, but to more generally assess the impact of standing crop and pollinator movement in this system.

To clarify my use of terminology, cross-pollination (resulting in xenogamy) refers to transfer of pollen among flowers on different plants, whereas self-pollination refers to transfer of pollen between flowers on the same plant (resulting in geitonogamy). The more restricted transfer of pollen from anthers to the stigma of the same flower is called auto-pollination (resulting in autogamy). Piper et al. (1914) found more seeds per pollination on average from cross-pollinated plants than from self- or auto-pollinated plants, but no difference in seed yield from auto-pollination versus self-pollination. In other literature, self-pollination of alfalfa may refer to auto-pollination (Barnes 1980), or to geitonogamy (Cooper and Brink, 1940, Tysdal et al. 1942, Pankiw and Boulton 1965, Holland and Bingham, 1994). Others have used the term "self-pollination"

without distinguishing whether autogamy or geitonogamy was involved (Sayers and Murphy 1966).

Materials and Methods

Greenhouse Experiments on Pollinator Movement. From February through April 1997, 2 assistants and I conducted a greenhouse experiment that included all 6 combinations of 3 pollinator movement patterns (simulated with hand pollinations) and 2 flower standing crop treatments (Table 1) in a factorial randomized complete block design with subsampling. We used a row of 10 potted alfalfa, 'Arrow', plants for each treatment combination. Treatment combinations were randomized over 6 rows, a total of 60 plants, on 1 greenhouse table. This arrangement was repeated 3 times on 3 different tables in the greenhouse, treating each table as a block in a randomized complete block design.

We dug alfalfa crowns from a research field and grew them in plastic pots (15 cm in diameter and 20 cm tall). Hand pollination treatments began when the plants started to bloom, and continued for 3 wk. To pollinate the flowers, a paper soda straw was cut at an angle, forming a pointed tip, which was inserted at the base of the keel and standard petals of the flower. When the flower was tripped, autogamous pollen was added to geitonogamous and xenogamous pollen accumulating on the concave inner surface of the straw from previously tripped flowers. Pollen from other flowers on the same plant, and from flowers on different plants, was present in varying proportions, depending on the order in which flowers had been previously visited. Concurrently, pollen was deposited on the stigma in varying proportions of autogamous, geitonogamous, and xenogamous pollen. A different

straw was used for each treatment combination in each block throughout the experiment, with pollen accumulating each day on the previous day's accumulation.

To manipulate flower standing crop, I took advantage of the variability in longevity of alfalfa flowers, which depends on pollination status (see introduction). Thus, flower standing crop is greater when there are few pollinators (Strickler 1997, Strickler and Freitas 1999). The high standing crop treatments received 30 hand pollinations of individual flowers per 10-plant treatment per day, simulating a small "bee" population (Table 1). With so few pollinations, untripped flowers accumulated and remained open for several days, creating a high standing crop of open flowers. From a distance, rows of plants receiving the high standing crop treatment were noticeably pink in coloration from the abundance of blooming racemes. Pollinations of all open flowers per treatment each day simulated a large "bee" population and a low standing crop. (Note the inverse relationship between flower standing crop and bee population.) This is because no flowers remained open for >1 d. The numbers of flowers pollinated in this treatment varied from day to day and was not specified in advance, but they were usually >30 and <250 (see *Results*). From a distance, rows of plants receiving the low standing crop treatment lacked an obvious pink coloration of their racemes.

TABLE 1. Description of treatments for alfalfa pollination greenhouse experiments

Treatments[a]		Plants per treatment per block	Flowers pollinated per treatment per day[b]	Movement rules for hand pollinations
Standing crop	Movement pattern			
High	Min.	10	30[c]	Pollinate all open flowers on a plant, then move to the next plant, until 30 flowers are pollinated. Thus, 1 to a few plants receive pollinations each day.
High	Intermediate	10	30	Pollinate ≤2 flowers per raceme, ≤3 racemes, for a total of ≤ 6 flowers per plant, then move to the

[a] See *Materials and Methods* for explanation. Movement pattern reflects the amount of cross-pollination.

[b] Pollinated flowers wilt, unpollinated flowers remain open ≈ 5 d.

[c] Simulates a small bee population.

Treatments[a]		Plants per treatment per block	Flowers pollinated per treatment per day[b]	Movement rules for hand pollinations
Standing crop	Movement pattern			
				next plant, until 30 flowers are pollinated. Thus, ≤6 flowers pollinated on ≥5 plants per day
High	Max.	10	30	Pollinate 1 flower, then move to the next plant until 30 flowers are pollinated. Thus, 3 flowers pollinated per plant per day.
Low	Min.	10	All open[d]	Pollinate all open flowers on a plant, then move to the next plant, until al open flowers are pollinated.

[d] Simulates a large bee population.

Treatments[a]		Plants per treatment per block	Flowers pollinated per treatment per day[b]	Movement rules for hand pollinations
Standing crop	Movement pattern			
Low	Intermediate	10	All open	Pollinate ≤2 flowers per raceme, ≤3 racemes for a total of ≤6 flowers per plant, then move to the next plant, rotating until all open flowers are pollinated.
Low	Max.	10	All open	Pollinate 1 flower, then move to the next plant, rotating until all open flowers are pollinated.

Movement rules for the hand pollination treatments (described in Table 1) simulated different possible pollinator movement patterns within and between plants in each treatment. These movement patterns were expected to result in different degrees of cross and self-pollination: the minimum movement pattern having the minimum amount of cross-pollination, the maximum movement having the maximum amount of cross-pollination, and so on. The intermediate movement pattern was an approximation of the actual movement of *M. rotundata* between alfalfa flowers, based on casual observation in alfalfa fields during the previous summer. For all treatments the starting plant was chosen randomly each day, and direction of movement from the starting plant alternated each day. Thus, the actual numbers of plants receiving pollinations, and the number of flowers pollinated on each plant each day was a stochastic process depending on flower availability as well as movement pattern.

After 3 wk of daily hand pollinations we removed all newly budding racemes from the plants, and pods were left to mature for 3 wk. When pods were mature, we harvested the racemes. For each plant, we randomly chose a sample of 15 racemes (or all racemes if plants produced fewer than 15) and recorded the number of pods, seeds, and bracts from each raceme. Bracts indicate the former attachment of a flower, and the ratio of pods to bracts indicates the proportion of flowers that developed pods. We estimated seeds per pod for the sample of 15 racemes by dividing the number of seeds per raceme by the number of pods on each raceme, then took the mean of the quotients. A 200-mg sample of seed was also collected from each plant. Number of seeds in the sample was counted and

divided into 200 mg to calculate average weight per seed.

Results were analyzed in a mixed model analysis of variance (ANOVA) using PROC general linear model (GLM) in SAS (SAS Institute 1989). Average values for each of the 10 plants in each treatment combination were calculated for seeds per pod, seed weight, flowers per raceme, and proportion of flowers developing pods (percent pollination). The dependent variables seeds per pod and seed weight were analyzed without transformation. Total racemes per plant, and flowers per raceme, were log transformed. Proportion of flowers developing pods was by transformed by the arcsine of the square root of the proportion (Zar 1984). Block was a random effect, whereas standing crop and pollinator movement treatments were fixed main effects in the ANOVA. The block x standing crop x movement interaction mean square was used as the error term to test the main treatment effects and their interaction.

If the effects of bee movement on seeds per pod were as hypothesized in the introduction, the result of interest would be a significant standing crop x movement interaction term because of the fewest seeds per pod produced in the minimum movement treatment when standing crop is high. Seeds per pod for the intermediate movement treatment should be less affected by standing crop, and the maximum movement treatment should show the smallest difference, if any, between high and low standing crop treatment.

Field Observations of Alfalfa Leafcutting Bee Movement. To determine if the movement of bees was similar to the movement patterns used in the greenhouse experiment, we observed *M. rotundata*

females foraging in 3 small (0.27, 0.60, and 1.36 ha) research fields planted with Arrow alfalfa. When a female landed on a raceme, we recorded the number of flowers tripped on that raceme. We also recorded whether the next raceme visited was on the same plant or a different plant. Observations were made early (24 June-7 July 1997) and late in the season (17-23 July 1997) when standing crop was high and low, respectively. Differences in bee movement on plants in different fields were minor and generally not significant compared with differences between early and late season, and were not the focus of this study. Therefore, bee movement data from the 3 fields were pooled.

We also estimated the number of open flowers per raceme available to the bees on 1, 2, 3, and 7 July during the early sampling period (high standing crop), and on 17 and 22 July during the late sampling period (low standing crop). We sampled 120 stems each day, recording the numbers of open, untripped flowers on each of the top 3 blooming racemes per stem, where most open flowers are found. Differences in available flowers between fields were not significant compared with differences between early and late season, and were not the focus of this study. Therefore, flower data for all dates and fields within each time period (early and late) were pooled.

The distribution of bees moving between 2 racemes on the same versus different plants was compared for high and low standing crops using chi-square contingency analyses. The distribution of numbers of flowers visited per raceme was compared for high and low standing crop using log-likelihood ratio contingency analysis (Zar 1984).

Pollen Carryover: Seed Set in a Sequence of Manual Self-Pollinations. One premise of the greenhouse experiment on standing crop and movement pattern was that seeds per pod should decrease as more flowers are pollinated in succession on the same plant. In 1998 I performed 2 independent experiments to determine whether and how seeds per pod decrease with increasing numbers of self-pollinations (i.e., as the potential for geitonogamy increases). By starting with abundant pollen from other plants, the 1st few pollinated flowers on a given plant should be primarily cross-pollinated. Eventually, however, pollen from the chosen plant should cover the mound of pollen at the tip of the straw where the stigma impacts, so flowers should be primarily self-pollinated. This should result in fewer seeds per pod as more flowers are pollinated in sequence. To test this hypothesis, I grew 15 potted alfalfa crowns to bloom in the greenhouse. When a plant had a minimum of 7 racemes with recently opened flowers in bloom simultaneously, I hand pollinated a sequence of flowers with straws, as described above. First, I pollinated a series of flowers on other plants in the greenhouse, so that pollen for cross-pollinations was abundant in the straw. On the experimental plant, I tripped 1-2 recently opened flowers (>3 h and <2 d since the flower opened) per raceme in a sequence of 12 flowers. On the racemes with hand pollinations I removed all unpollinated flowers and buds. I tied different colored embroidery threads around the base of these racemes, to indicate the pollination order. As a control, 2 flowers on the same plant were auto-pollinated by squeezing them with a forceps. Two or 3 series of flowers were pollinated on each plant over a 4-wk period. Pods were

harvested when seeds had developed, and seeds per pod were recorded.

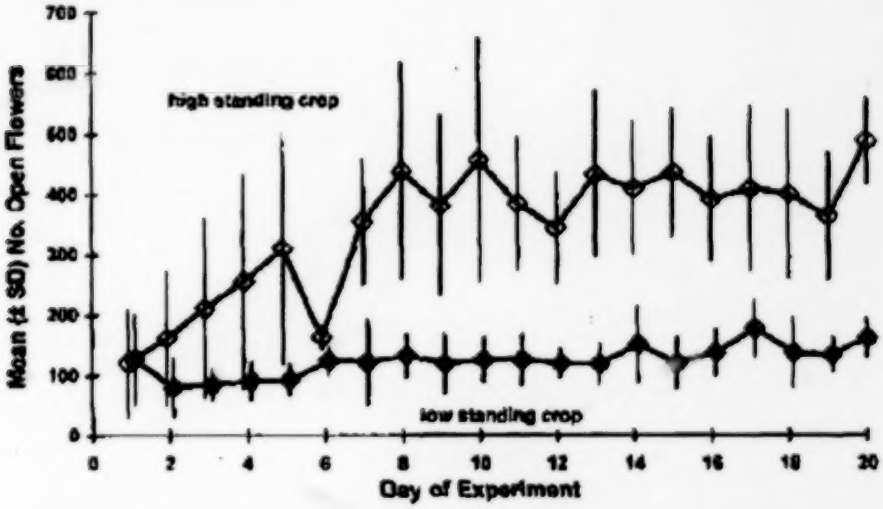

Fig. 1. Standing crop of alfalfa flowers (number of open flowers; mean ± SD; n = 9 for each treatment) over time (days since start of hand pollinations) for the 1997 greenhouse experiment. The high standing crop treatment (◇) had 30 flowers pollinated daily per treatment. The low standing crop treatment (◆) had all flowers pollinated daily.

I repeated the experiment with 22 plants growing in the field during the summer of 1998. On each plant assistants helped pollinate 20 flowers in succession, 2 per raceme on 10 racemes. Only 1 sequence of flowers was hand pollinated per plant. As in the greenhouse, the pollination sequence began with fresh pollen from other plants. On the racemes with hand pollinations, all unpollinated flowers and buds were removed and colored embroidery threads were used to mark pollination order of the racemes. Two flowers per plant were also auto-pollinated. I harvested pods when seeds had developed, and recorded seeds per pod.

Analysis of variance was used to compare seeds per pollinated flower, where pairs of flowers in the sequence (e.g., 1+2, 3+4, and 5+6) were treatments and individual plants were blocks in a randomized complete block design. Separate analyses were done for greenhouse and field data. For analysis of the greenhouse data, average seeds per pod were calculated for each sequence pair on each plant. PROC GLM in SAS was used for the analysis (SAS Institute 1989). Groups of treatment means were compared using the Tukey studentized range test in GLM.

Results

Greenhouse Experiments. As planned, standing crop of open flowers was high for the simulated small "bee" populations (30 flowers pollinated per 10-plant replicate per day) and low for the large "bee" populations (all open flowers pollinated each day; Fig. 1). An average of 127 ± 53 SD flowers opened per day in the low standing crop treatments. All of these flowers were pollinated. Meanwhile, mean number of open flowers per day in the high standing crop treatments increased as open, unpollinated flowers accumulated during the 1st wk of the experiment and then leveled off when wilting flowers equaled newly open flowers (Fig. 1). Mean number of open flowers averaged 349 ± 162 SD, indicating greater variance as well as a larger mean in the high standing crop treatment.

The number of racemes that had bloomed per plant by the end of the experiment was less variable than was the day-to-day standing crop of open flowers (Fig. 2A). There were no significant differences in total racemes between standing crop or movement treatments. An ANOVA was not significant ($F = 1.10$;

df = 17, 162; $P = 0.36$). Similarly, analysis of average number of flowers per raceme (Fig. 2B) showed no significant differences between standing crop treatments, movement treatments, or their interaction (all $P > 0.7$). These results indicated that standing crop differences were not the result of differences in overall flower production of the plants.

A significantly greater proportion of flowers in the low standing crop treatment developed pods than in the high standing crop treatment (mean ± SE: 48.9 ± 1.1% and 28.2 ± 1.0% respectively; $F = 159.8$; df = 1, 10; $P < 0.001$; Fig. 2C). This difference reflects the number of pollinations per day for the standing crop treatments, and thus is an artifact of the experimental design rather than a test of the hypothesis. Interestingly, although all flowers were pollinated in the low standing crop treatment, on average more than half of them did not develop pods.

Seeds weighed slightly but significantly more for the high standing crop treatments (2.4 ± 0.03 [SE] mg) than for the low standing crop treatments (2.2 ± 0.03 mg; $F = 15.06$; df = 1, 10; $P < 0.003$). There was no significant difference between movement patterns ($F = 4.03$; df = 2, 10; $P = 0.052$) and no significant interaction between standing crop and movement treatments ($F = 0.19$; df = 2, 10; $P = 0.83$) .

Most important for this study was the average number of seeds per pod under different standing crop and movement treatments. Average seeds per pod ranged from 2.86 ± 0.19 (SE) for the high standing crop-minimum movement treatment to 4.23 ± 0.17 for the low standing crop-maximum movement treatment (Fig. 3). Significantly more seeds per pod resulted when standing crop was low (4.03 ± 0.10) than when

standing crop was high (3.36 ± 0.10; Table 2; Fig. 3). Seeds per pod were not affected by movement pattern (P = 0.235; Table 2). The difference between standing crops was greatest for the minimum movement treatment (1.20 fewer seeds per pod) and had a lesser effect for the intermediate (0.28 fewer seeds per pod) and maximum (0.53 fewer seeds per pod) movement treatments. These differences reflect trends in the expected direction if bee movement increases geitonogamy. However, the standing crop x movement interaction term was not significant (P = 0.282; Table 2) because of variability among plants and among blocks. The minimum detectable difference (Zar 1984) for the interaction term, given the observed error mean square, and assuming α = 0.05 and β = 0.2, was ≈1.7 seeds, whereas the actual difference was 0.92 seeds (1.20-0.28 fewer seeds per pod). To detect a 1 seed difference in the interaction term would have taken 10 replications (blocks) in the experiment rather than the 3 replications actually performed. The time and labor required for adding even 1 block to the experiment was prohibitive. Thus, the experimental design proved inadequate for detecting the expected interaction between standing crop and movement treatments. It was effective, however, at detecting a significant effect of standing crop treatment.

Field Observations of Alfalfa Leafcutting Bee Movement. Seventy-two raceme visits were observed when standing crop was high in early season, and another 72 were observed when standing crop was low in late season. The percentage of bees moving between 2 racemes on the same plant when standing crop was high was not significantly different from the percentage when was standing crop low (46% versus 44%; X^2 =

0.03, df = 1, $P > 0.75$, $n = 144$). Overall averages were 45% of the moves within a plant and 55% between plants. There was a significant difference in the distribution of numbers of flowers visited per raceme for high versus low standing crops ($G = 18.66$, df = 54, $P = 0.001$, n = 144; Fig. 4). Although almost 60% of the bees visited only 1 flower per raceme when standing crop was high, some visited asmanyas 8 flowers per raceme. In contrast, when standing crop was low, ≈80% of bee visits were to only 1 flower per raceme and no bees visited >3 flowers per raceme.

A total of 1,440 racemes with open flowers was available on 480 sampled stems during the 4 d high standing crop observation period, and a total of 115 racemes with open flowers was available on 240 sampled stems during the 2 d low standing crop observation period. The distribution of flowers visited per raceme by bees is probably related to a difference in the number of open, untripped flowers available per raceme (Fig. 5). When standing crop is high, there were many racemes with >.3 open flowers, including occasional racemes with up to 27 open flowers. When standing crop is low, few racemes had >.3 open flowers, and none had >14. The bees do not systematically visit all open flowers on a raceme during 1 visit, because bees visited a maximum of only 8 flowers per raceme. However, when standing crop is low, most available racemes had 3 or fewer flowers in bloom, requiring bees to move more between racemes.

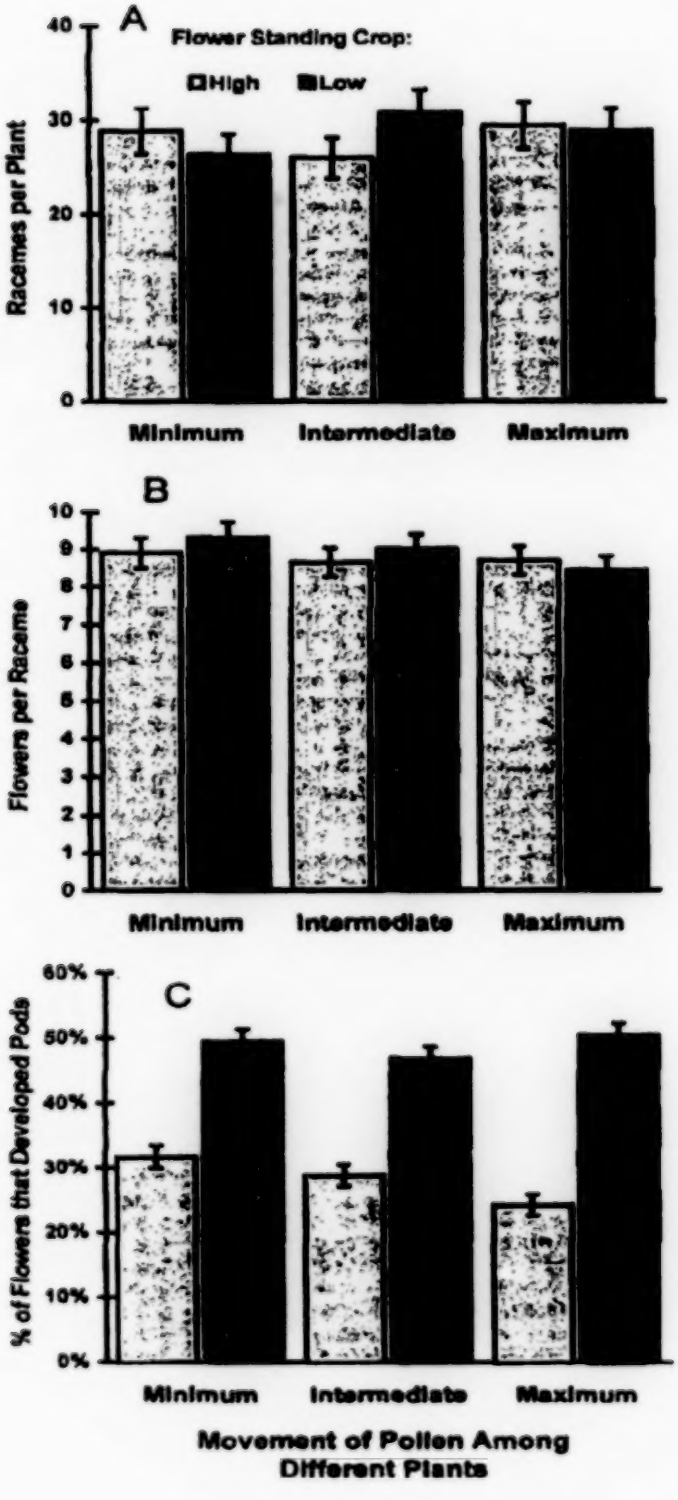
A
Flower Standing Crop:
High
Low
Racemes per Plant
40
30
20
10
0
Minimum
Intermediate
Maximum
B
Flowers per Raceme
10
9
8
7
6
5
4
3
2
1
0
Minimum
Intermediate
Maximum
C
% of Flowers that Developed Pods
60%
50%
40%
30%
20%
10%
0%
Minimum
Intermediate
Maximum
Movement of Pollen Among Different Plants

Fig. 2. Comparison of reproductive characteristics of the treatments involved in the 1997 greenhouse alfalfa pollination experiment. Error bars indicate standard errors. (A) Mean number of racemes per plant at the end of the experiment. (B) Mean number of flowers per raceme. (C) Percent pollination (number of pods divided by number of bracts x 100).

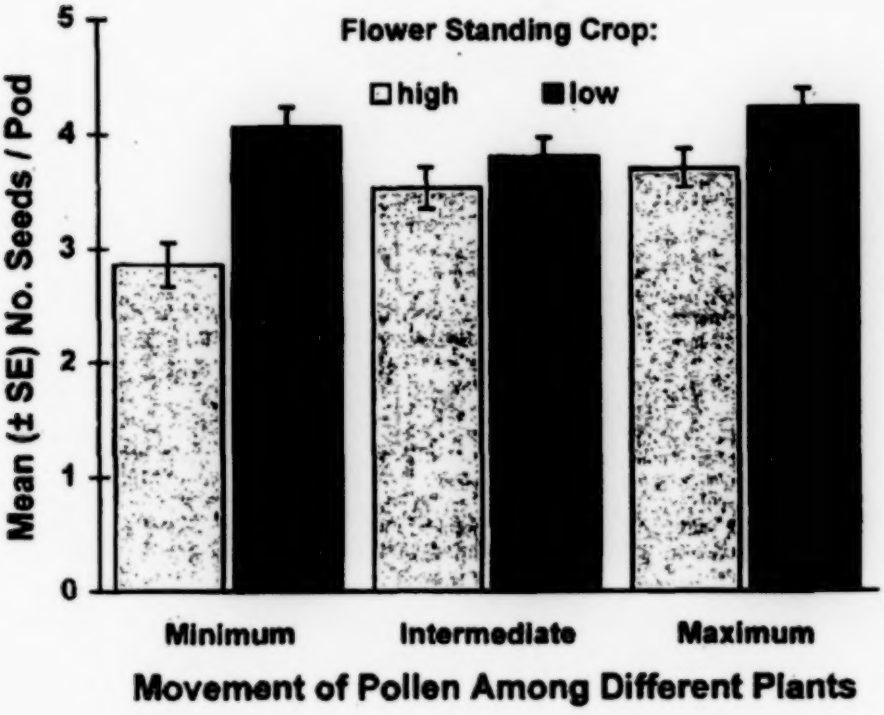

Fig. 3. Comparison of mean seeds per pod for alfalfa pollen movement and flower standing crop treatments. Error bars indicate standard errors.

Table 2. Analysts of variance results for seeds per pod for alfalfa pollination experiments

Source of variation	Sum of squares	*F*	Df	*P*
Model	762.5	3.58	17	<0.001
Block	24.5	0.98	2	0.379
Standing crop[a]	272.7	8.70	1	0.015
Movement[b]	105.5	1.68	2	0.235
Standing crop × movement	90.5	1.44	2	0.282
Bloc × standing crop × movement[c]	313.6	2.50	10	0.008
Error	2,032.3		162	
Total	2,794.8		179	

[a] High versus low standing corp.

[b] Minimum, intermediate, and maximum movement pollen among plants.

[c] The mean square for this interaction was the error term used to test the standing crop and movement effects and interaction.

Pollen Carryover: Seed Set in a Sequence of Manual Self-pollinations. There were significant differences in seeds set for different pairs of sequentially tripped flowers on the same plant in both the greenhouse experiment ($F = 4.73$; df = 6, 82; $P < 0.001$) and the Field experiment ($F = 7.47$; df = 10, 168; $P < 0.001$). On average, seeds per pollination decreased by 1.0 for flowers tripped after the 1st pair in the greenhouse (Fig. 6A), and by 1.7 for flowers tripped after the first 2 pairs in the Field (Fig. 6B). In Field

and greenhouse experiments, auto-pollinated flowers averaged >1 seed per pollination, which is less than any of the hand-pollinated flowers averaged. Multiple comparison tests indicate that seeds per pod gradually decreased as more flowers were pollinated on a plant, especially in the field experiment. However, small sample sizes and high variability among plants limited my ability to detect significant differences, except between the first few flowers and some of the later flowers pollinated (Fig. 6B). Presumably, the 1st pollinated flowers produced the highest proportion of xenogamous seeds and subsequent flowers produced a higher proportion of geitonogamous seeds.

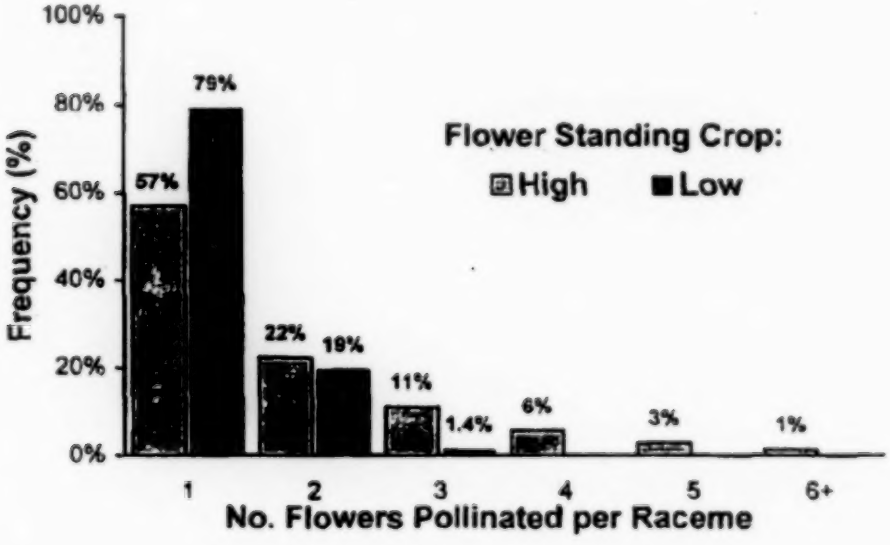

Fig. 4. Distribution of number of alfalfa flowers pollinated per raceme by foraging female *M. rotundata* when standing crop of open flowers is high versus low.

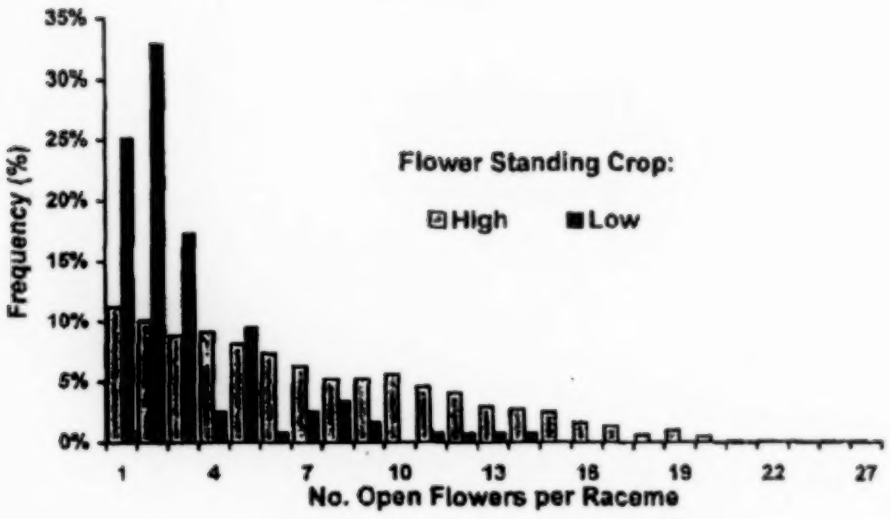

Fig. 5. Distribution of open alfalfa flowers per raceme when standing crop of open flowers is high versus low.

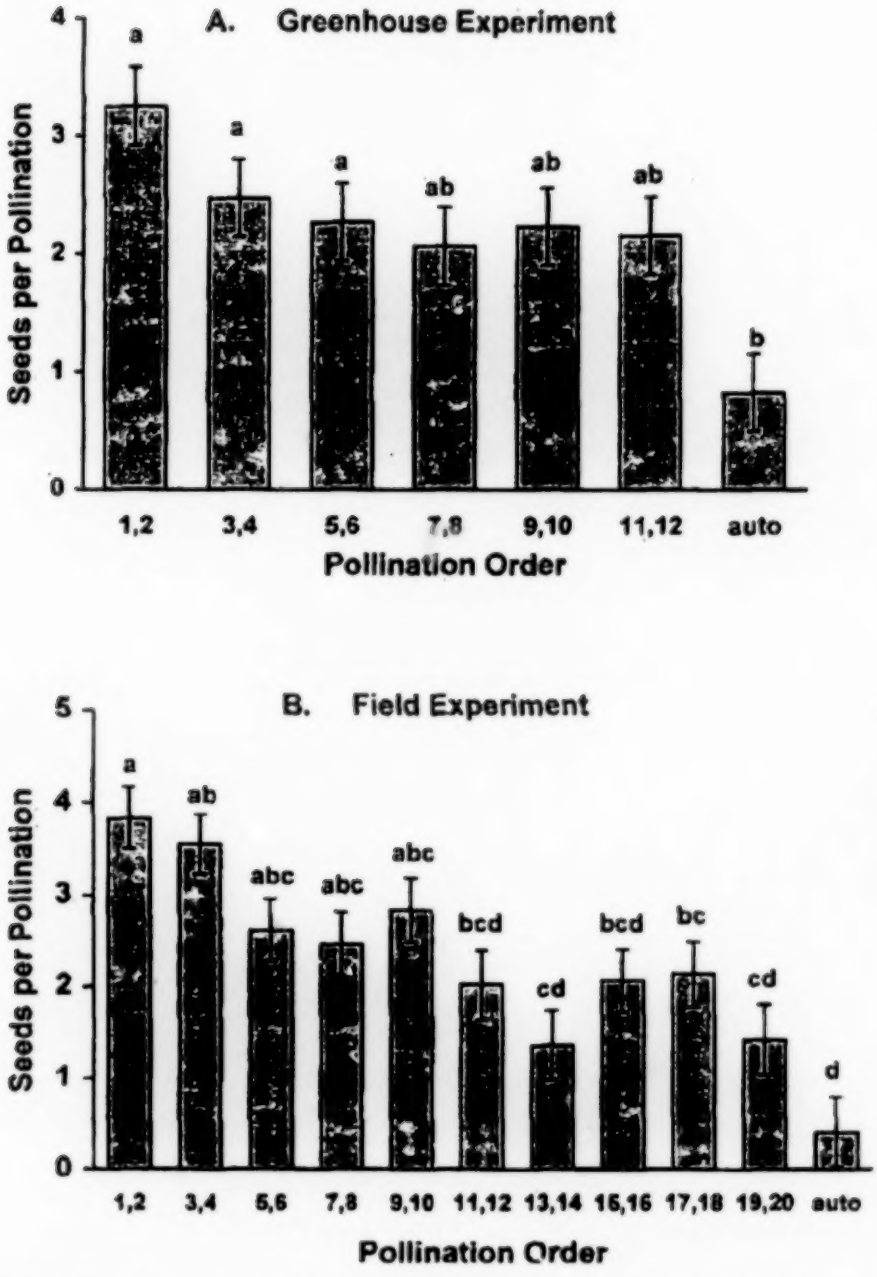

Fig. 6. Mean number of alfalfa seeds per pollination in a series of successive pollinations between flowers on the same plant. Error bars indicate standard errors. Hand pollinations began with outcrossing pollen.

Seeds per pollination for autopollination are presented for comparison. (A) Succession of 12 flowers pollinated per potted plant ($n = 15$) in the greenhouse. (B) Succession of 20 flowers pollinated per plant ($n = 22$) in the field. For each experiment, bars with the same letter are not significantly different by Tukey studentized range test.

Discussion

In the greenhouse experiment, high and low standing crops of open flowers were created by manipulating the number of pollinations per day in each treatment (Fig. 1). This was equivalent to having small and large populations of pollinating bees, respectively. When only 30 flowers were pollinated, standing crop was high because blooms persist for up to 1 wk if not pollinated (Carlson 1928, Vansell and Todd 1946). When all open flowers are tripped, standing crop drops because pollinated flowers quickly wilt (Vansell and Todd 1946). The only flowers open on a given day are those that opened after hand pollinations were performed the previous day. Differences in standing crop were not related to any differences in total production of flowers (Fig. 2 A and B), but rather were determined primarily by the rate at which flowers were pollinated. The low standing crop treatments yielded slightly lighter seeds than the high standing crop treatments, probably the result of greater competition for assimilates when more seeds are produced. Only 50% of the flowers actually set seed when all flowers were pollinated (Fig. 2C), suggesting an upper limit to the ability of the plant to invest in seed set. This result is consistent with similar

results for *Lotus corniculatus* L., another papilionaceous legume (Stephenson 1984).

More seeds were produced per pod when standing crop was low than when standing crop was high (Fig. 3). The difference was greatest in the minimum movement treatment, though not significantly so. For the minimum movement treatment, geitonogamy might explain differences between high and low standing crops. However, movement pattern cannot explain a reduction in seed yield between high and low standing crop for the maximum movement treatment. An alternative explanation, allocation of limited resources, should lead to fewer seeds per pod in the low standing crop treatment, rather than the other way around. Perhaps production of more pods in the low standing crop treatment as compared with the high standing crop treatment stimulates more seed production in each pod. More likely, straws used in hand pollinations would have accumulated more pollen in the low standing crop treatment where all flowers were pollinated than in the high standing crop treatment where only 30 flowers were pollinated per day. If more pollen on the straw is correlated with more pollen, especially outcrossing pollen, deposited on flower stigmas, then seed set would be greater for the low standing crop treatment under all movement patterns. Whether bees show a similar increase in pollen accumulation the more flowers that they visit, and what impact this has on seed production, is unknown.

Whatever the reason, a 20% greater seed production when standing crop is low suggests that there could be an advantage to introducing bees into alfalfa seed fields as the flowers are first coming into

bloom. Early pollination should prevent open flowers from accumulating on racemes, decreasing the standing crop of open flowers, and thus maximizing the number of seeds per pod.

In a separate pollen carryover experiment, manual pollinations demonstrated a significant reduction in seed yield as more flowers were pollinated per plant (Fig. 6). This result suggests that geitonogamy should, in fact, reduce seed yields, if only slightly. The fewest seeds per pollination resulted from auto-pollination, though the number was not significantly different from the last hand pollinated flowers in a sequence of 12 or 20 flowers. Hand pollinated flowers produced more seeds per pollination in these experiments than the 0.49 seeds per pollination reported in the literature for a series of 100 self-pollinations with the variety Arrow (Holland and Bingham 1994), presumably with no cross-pollen available. Thus, even after 20 flowers were pollinated in succession on 1 plant, there was still a substantial amount of xenogamy occurring from the initial foreign pollen on the straw. Models of pollen carryover (Lertzman and Gass 1983), as well as some field studies (Geber 1985, Robertson 1992) suggest that carryover of outcrossing pollen can be substantial, and may mitigate some of the effects of pollinator movement within a plant. Relatively high carryover of outcrossing pollen may have contributed to our inability to detect a significant effect of pollinator movement or a significant interaction between standing crop and movement (Table 2).

Patterns of pollen deposition are likely to be different on bodies of foraging bees than on straws. The straw probably presents a greater surface area for the staminal column to hit than does the underside of

the bee's body. The column apparently strikes the ventral surfaces of the bee's head and thorax (Michener 1953, Richards 1984). Huang et al. (1986) reported pollen accumulations on the propodeum and 1st abdominal tergite, although it is not clear if the alfalfa stigma contacts these surfaces in *M. rotundata*. The bee periodically grooms pollen from her head and thorax to the scopal hairs on the ventral side of her abdomen (Michener 1953, Richards 1984). This probably does not happen after each flower, but its frequency and thoroughness is unknown. Grooming might reduce the amount of pollen available for cross-pollinations, or it might expose pollen from previous plants that had been buried after a series of visits to flowers on the same plant (Lertzman and Gass 1983). In our hand pollinations, we did not sweep pollen off of the straw, although pollen was observed to drop off the straw periodically. This could account for some of the variability that we observed in seeds per pod. Thus, it is not clear whether hand pollinations produced more or less cross-pollination than occurs with bees. Further directed observations of bee behavior may answer the question.

In the alfalfa field, do bees visit enough flowers in succession on the same plant that seed production might be affected if geitonogamy significantly reduces seed production? *M. rotundata*, the main pollinator in commercial alfalfa seed fields in the northwestern United States, moves within a plant more often when there are many flowers in bloom per raceme, than when there are few flowers in bloom per raceme (Figs. 4 and 5). This is because more flowers are visited per raceme rather than a greater probability of moving between racemes on the same plant when standing

crop is high. Even so, bees tripped 4 or more flowers on only 10% of the racemes visited when standing crop was high (Fig. 4). With a 55% chance of moving to another plant, *M. rotundata* would rarely visit as many as 30 flowers, or even 12 flowers in succession on that plant. Thus, differences in seed production between high and low standing crop are probably affected little by geitonogamy. Other factors, however, may be important in reducing seeds per pod when standing crop is high.

In conclusion, a high standing crop of open flowers is determined in part by the amount of pollination that occurs (i.e., by the size of the bee population) and may reduce seed production in alfalfa. Geitonogamy because of bee movement within plants when standing crop is high seems to have a small effect. There may still be an advantage to releasing bees into alfalfa fields as bloom begins, when standing crop is still low, rather than waiting until flowers accumulate on racemes creating high standing crop. Early release of bees should promote pollination, minimize the standing crop of open flowers, and thus maximize seed production.

Acknowledgments

The following assistants helped gather the data for this study: Crystal Booth, Julie Sellers, and Janet Lewis helped with greenhouse hand pollinations. Cody Cleaver followed leafcutting bees in the field. Crystal Booth, Shaun Malone, Tom Ireland and Chelsea Findley assisted with hand pollinations in the field. Comments from several colleagues at University of Idaho and 2 anonymous reviewers were helpful for improving the manuscript. This research was supported by the USDA National Research Initiative

Competitive Grants Program, Grant No. 96-35311-3729, by USDA Cooperative Agreement 58-5428-5-113, and by the Idaho Alfalfa Seed Commission. This is Idaho Agricultural Experiment Station publication No. 98729.

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Received for publication 23 December 1998; accepted 7 June 1999.

JA-527

Summary of 2000 Alfalfa Pollen Flow Experiment

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Forage Genetics International

Abstract

An alfalfa pollen flow study was conducted during the summer of 2000 by Forage Genetics International in association with members of the Regulatory Affairs Committee of the North American Alfalfa Improvement Conference. The study was designed to measure pollen flow potential between adjacent alfalfa seed production blocks using leafcutter bees as the predominant pollinator species and to assess the efficacy of current alfalfa seed production field isolation requirements. Pollen flow was measured using a dominant, transgenetic marker (the Roundup Ready® gene) in the pollen source plants. Non-transgenic alfalfa was planted in replicated pollen trap plots at 500, 1000 and 1500 ft from the source field edge; fallow ground surrounded these plots. A non-replicated trap plot was planted at 2000 ft; the intervening land planted to onions and winter wheat. Pollen flow was estimated as 1.39, 0.32, 0.07, 0.00% at 500, 1000, 1500 and 2000 ft, respectively. In addition to the stocked, leafcutter bees, native honeybees were also present in the field and both likely contributed to pollen flow. Findings from this study infer that alfalfa seed production plots may be significantly insulated from undesired pollen flow using spatial isolation (distance ≤900 ft) in combination with non-fallow cropping of the isolation zone and adherence to recommended pollinator management.

Introduction

The amount of potential pollen flow between adjacent alfalfa seed production fields is a key factor in setting isolation requirements for seed stock production. Current isolation requirements are based on data collected in the 1980's, which used pest resistance genes as pollen flow markers between seed production fields (Brown, *et al.* 1986). Recently, Kansas State University and USDA scientists used naturally occurring alfalfa marker genes to measure the potential for gene flow from source blocks to alfalfa plants at various distances from the source (St. Amand, *et al.* 2000). The experiment is useful in estimating the likely escape of transgenes to feral alfalfa plants during commercial seed production. The current study was designed to measure likely pollen flow between transgenic and non-transgenic seed production fields. This data should be useful in helping set isolation guidelines for the commercial seed production of transgenic alfalfa varieties. The importance of unintended gene flow between adjacent seed fields and to feral alfalfa is receiving renewed attention as the U.S. alfalfa seed industry prepares for commercialization of the first transgenic alfalfa varieties.

The issue of gene flow has been extensively discussed by the Regulatory Affairs Committee of the North American Alfalfa Improvement Conference. A better understanding of pollen flow will enable the Regulatory Affairs Committee of the NAAIC to contribute technical expertise in the national discussion on guidelines for commercial release of transgenic alfalfa. In 1998-1999, the Committee declared the need to begin experiments to assess the potential for

pollinator-mediated movement of alfalfa genes/transgenes during commercial seed production. Based on input from the committee, this experiment was designed to measure alfalfa pollen and gene flow under conditions typical for Pacific Northwest seed production using leafcutter bees as pollinators. The Roundup Ready® (RR) trait offers unique benefits as a marker gene for the study of gene flow between seed production fields. The RR trait is controlled by a single dominant transgene, which allows for easy identification of progeny arising from the transgene-marked pollen. An efficient seedling screen for the RR phenotype was previously developed that allows rapid identification of the marker gene.

Methods

Field Plot Design The Roundup Ready® (RR) transgene (Padgette *et al.*, 1996) was used as a marker to measure gene flow from a 1 acre RR source plot to non-RR trap plots planted at four distances from the source plot (Figure 1). In order to meet current UDSA isolation requirements for the field release and accommodate the study size to available land resources, the replicated treatments (isolation distances between source and trap blocks) were designed to radiate in a single, westerly direction at 500, 1000 and 1500 ft from the source block. The field site did not have an anticipated, prevailing wind direction during the months of pollinator activity. The land between and surrounding the source and replicated trap plots was maintained as fallow. The fallow ground simulated a worst-case interplot management where bees would have no physical or visual barriers to movement and pollen flow would be enhanced (i. e. exaggerated as compared to actual field

management conditions). In contrast, the 2 acre, 2000 ft trap plot was offset from the first series by approximately 45° southwest and other crops (winter wheat and onions) were grown on the intervening land. The latter, non-fallow management being typical for alfalfa foundation seed production in the Pacific Northwest Region of the U.S.

The study was established April 7, 2000 (USDA notification #00-053-07n). Field crops surrounding the study and the location of the 2000 ft trapare shown in Figure 2. The plots were seeded as follows: All plots- 1 lb seed /A and 36 inch row spacing; Trap plots- cultivar "DK 180ML," 35 ft x 36 ft each for replicated plots and 435 ft x 200 ft (2 acres) for the 2000 ft non-replicated trap; and, Source plot-seeded with a RR experimental line "JRR99-lot ND," 435 ft x 100 ft source (1 acre). The alfalfas have similar fall dormancy reactions-FD8 and FD7, respectively. JRR99 is a non-commercial seed lot developed specifically for this study. JRR99 is Syn1 generation seed produced by the open pollination of simplex (Aaaa) RR parent plants. RR trait phenotypic expression in the Syn1 is predicted to be 75%, with genotypic array- 1 AAaa: 2 Aaaa: 1 aaaa progeny.

Source plot seedlings were sprayed at the three trifoliolate leaf stage with 4 qt/A Roundup Ultra (glyphosate herbicide) to remove the 25% null segregants. Two weeks after herbicide application, 26.6% of the source plot seedlings were counted as killed (data not shown). The surviving pollen source plants therefore, had the RR genotypes AAaa or Aaaa, estimated to occur in 33% and 67% of the RR population, respectively.

Weeds were controlled in the source plot with a single, additional application of Roundup Ultra (2 qt/A) and were controlled in the trap plots with hand tools. Plots were furrow irrigated. Leafcutter bees were introduced when the plots were at 25% bloom (June 20). The bees were removed after 4 weeks. Plants were sprayed with desiccant August 30 and seed was harvested Sept 15. Piots were harvested in the sequence: 2000', 1500', 1000', 500', and Source. The seed produced in the RR source plot was an open pollinated Syn2, "JRR99-Syn2." Each plot replicate was harvested as a 3 x 3 grid of 9 equal subplots. The 2-acre trap seed was harvested, bulked and subsampled nine times. After assay completion, all of the seed produced in this study was devitalized to prevent inadvertent transgene release.

Gene Flow Greenhouse Assay and Data Analysis One gram of threshed, scarified seed (ca. 460 seed/gram) was planted in each greenhouse 1020 flat in the FGI, Nampa, Idaho APHIS-approved greenhouses. Nine grams seed (1 g/subplot) were assayed for each of the replicated plots. Similarly, nine- 1 gram samples were assayed from the 2000 ft trap plot. Each assay flat also included one row of each the non-tolerant check (DK 180ML) and of the 2000 RR source plot produced seed (JRR99-Syn2). Seedlings were counted 6 days after planting and sprayed with Roundup Ultra (4 qts/A) at the three trifoliolate stage (17 days old). Final tolerance counts were taken 5 days after Roundup Ultra application. To validate tolerance results, tissue from all survivors at the 1500 ft plot distance (i.e. the six putative adventitious RR seedlings) was lab tested for the presence/absence of the RR protein (EPSPS-CP4) (Padgette *et al.*, 1996).

Alfalfa is an autotetraploid (2n=4x=32) with n=2x pollen. The source plot plants were not homozygous for the RR alleles. It is important to note that by tracking only the number of trap plot progeny marked with the RR phenotype (i.e. progeny that have resulted from either AA or Ax marked pollen), the observed %RR did not account for the additional, unmarked progeny which would have arisen from the source plot pollen that does not contain the dominant transgene (i.e. null pollen - xx, 42% of total source plot pollen). The pedigree of the source plot plants can be used to estimate their 4x genotypes, the 2n gametic genotypes and the proportion of each in the source population pollen pool (Table 2). Based on this information, it is possible to calculate the percentage of pollen carrying at least one copy of the transgene. Table 2 shows the calculations performed to estimate that 58% of the pollen produced in the RR source plot carries one or more copies of the transgene. Total gene flow potential is estimated by multiplying the %RR seed observed in the trap plots by an adjustment factor of 1.72 (i. e. 1/0.58) to account for the flow of null pollen from source plots.

Data were analyzed using Proc GLM of SAS (version 6.12, SAS Institute, Cary, NC) with variances partitioned into two sources, distance (500, 1000, and 1500 ft) and strip (reps 1, 2, 3 and 4). Variation due to distance was partitioned using orthogonal contrasts to test for linear and quadratic regression responses. An analysis of residuals was also performed to confirm that the assumptions of the variance analysis were met. Based on the results of F-tests (Type 1 error rate = 0.05), SAS Proc GLM was used to generate a linear prediction model.

Results and Discussion

No differences in pollen flow were detected among the four strips (replicates) (Table 1 and Table 3). As expected, pollen flow decreased as distance from the pollen source increased. There was an 80-fold decline in pollen flow for every 500' beyond the first trap plot. Total pollen flow was estimated to be 1.39%, 0.32%, 0.07% and 0.00% at 500, 1000, 1500 and 2000 ft, respectively. Using data from only the replicated plots, orthogonal contrasts revealed that the decline in pollen flow was linear; the quadratic partition was not significant. The best-fit linear prediction equation was estimated as: Pollen flow = 1.916 - 0.00132 (distance ft). The standard error (se) of the intercept and regression coefficients were 0.3010 and 0.0002787, respectively. Pollen flow at 900', the isolation distance used for production of Foundation Class seed was estimated to be 0.73% (se=0.117). The 95% confidence interval of this estimate was 0 - 1.64%.

In greenhouse flats, the mean percentage RR phenotype for the positive control (JRR99 Syn2) and negative control (DK 180ML) lines was 83% and 0%, based on 3,431 and 3,672 seedlings, respectively. RR phenotype in the greenhouse test was 100% correlated to positive laboratory tests for the RR protein (data not shown).

Summary and Conclusions

The data presented would support that the current Foundation Class seed field isolation distance of 900' is an effective limitation to significant gene flow between adjacent alfalfa seed production fields as <1% flow would be predicted under worst-case fallow, interplot management. In this study, several factors may have

(intentionally) encouraged or exaggerated gene flow above what might occur under actual alfalfa seed production practices. First, the field area planted to the RR source plants was three times greater than the collective area occupied by the small, replicated trap plots (1 ac vs. 0.35 ac). Second, the land between the source and replicated trap plots was left fallow so there was no visual or intercrop impediment to bee movement. Third, trap plots at the intermediate distances may have acted as a bridge for the bees between the source and those further away (therefore the effective isolation distance is less than 1000 or 1500 ft). No gene flow was detected in the 2000 ft trap that had been grown under actual field isolation production practices. Findings from this study infer that alfalfa seed production plots may be effectively isolated from undesired pollen flow using isolation in combination with non-fallow cropping of the isolation zone and adherence to recommended pollinator management.

Leafcutter bees are reported to have a maximum foraging radius of approximately 600 ft if there is sufficient alfalfa pollen available. Leafcutter bees were the intended pollinators in this study but routinely, native honeybees were also observed working the flowers. Honeybees are known to collect nectar and pollen at much greater distance from their hive. Honeybee flight distance estimates range from 1 to 5 miles depending upon the social cast of the bee and forage supply available to them. The present study was situated between two fields of corn (see Figure 2). Corn and corn pollen is highly attractive to honeybees. Although leafcutter bees may have been responsible for the most of the pollen movement at the shorter distances, we believe that the native honeybees may

have mediated a portion of the flow, especially at the 1500' trap distance. A blend of intended and native pollinators would be anticipated to occur in most commercial alfalfa seed production fields. Pollen will move according to the pollinator density, bloom abundance relative to pollinator density and the pollinator species present in the field.

Acknowledgements

Members of the Regulatory Affairs Committee of the North American Alfalfa Improvement Conference are acknowledged for their valuable contributions to the study design and review of the results. Thanks are expressed to Steve Bowley for statistical analysis of the data.

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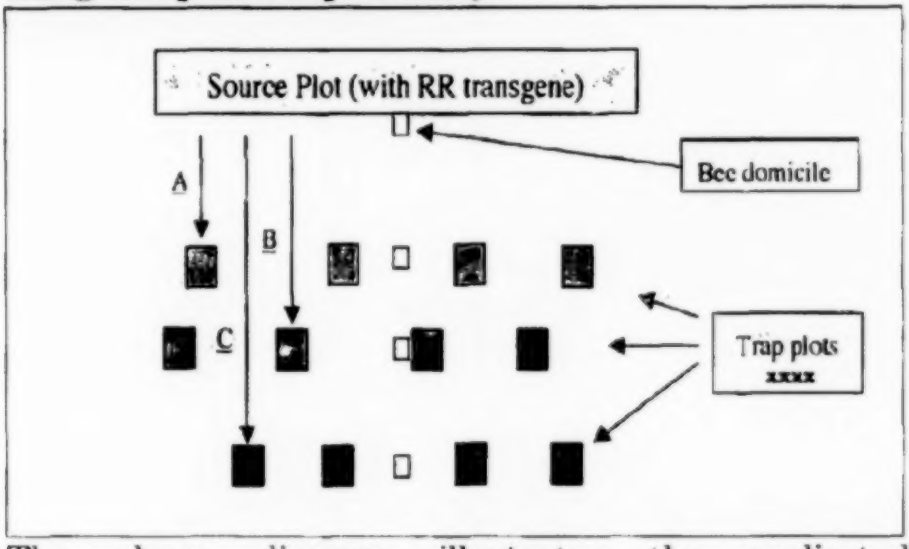
Figure 1. 2000 Alfalfa Gene Flow Study field plot design (replicated plots only)



The above diagram illustrates the replicated experimental design. Some critical parameters and criteria were as follows:

1) Distance between source plot and trap plots (distances between closest plot edges):
   a. 500 feet (A)
   b. 1000 feet (B)
   c. 1500 feet (C)
2) Plot size and alfalfa line description of the source and trap plots
   a. source plot—1 acre (435 ft x 100 ft); RR alfalfa (lot JRR99-ND)
   b. trap plots—0.03 acre (35 ft x 36 ft); non RR alfalfa—DK180 ML

   distance between plots in the same rep—ca. 90 ft
3) Number of trap replications—four (each harvested in 9 sections of equal size)

4) Leafcutter pollinator density and location — four domiciles-500' apart, similar density to commercial practices
5) Interplot cover — fallow

Figure 2. Field plot map and crops surrounding 2000 Gene Flow Study

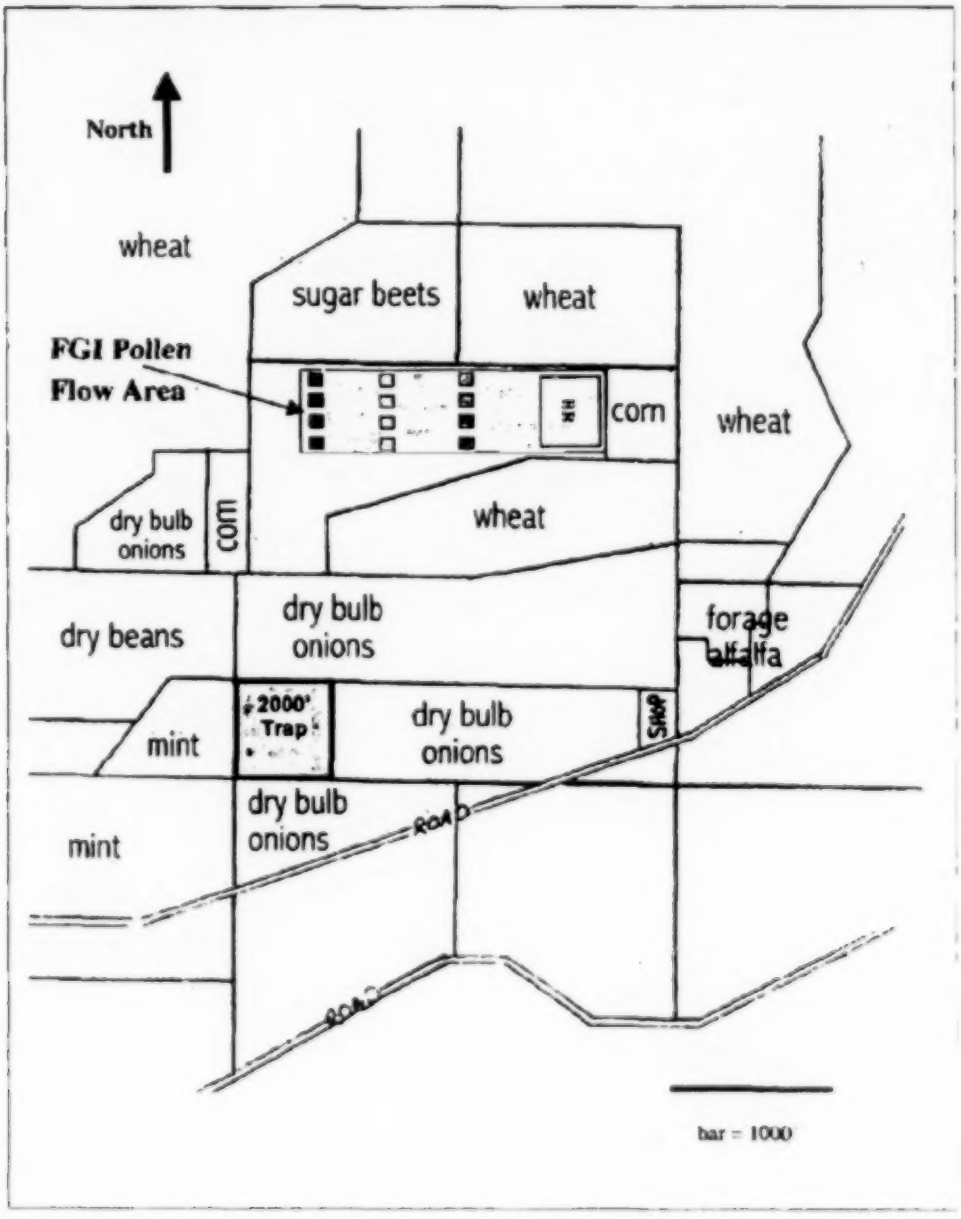


Table 1. Mean percent gene flow from alfalfa. Standard error (se) based on data from replicated plots at 500', 1000' and 1500', only.

Trap distance (ft)	Seedlings tested	Gene Flow (%)
500	14,675	1.39
1000	13,945	0.32
1500	15,446	0.07
2000	14,946	0.00
se		0.17

Table 2. Genotype of Roundup Ready alfalfa source plants and the proportional contribution of pollen to pool. Alfalfa is an autotetraploid (4x=32) with 2n pollen.

Genotype of Pollan (n=2x)	Genotype of RR Source Plant (4x)		Proportion of Total Source Plot Pollen Pool
	AAxx (0.33)	Axxx (0.67)	
AA	0.25	0.00	0.08
Ax	0.50	0.50	0.50
Xx	0.25	0.50	0.42

Table 3. Variance analysis of gene flow from alfalfa using a Roundup Ready transgene as a marker. Test was conducted in 2000 at Nampa, Idaho.

Source	df	Mean square	F	P>F
Strip	3	0.38045	1.05	0.4356
Distance	2	3.93502	16.33	0.0037
Linear	(1)	3.48533	28.93	0.0017
Quadratic	(1)	0.44970	3.73	0.1016
Residual	6	0.12048		

Gene flow in alfalfa under honey bee (*Apis mellifera*) pollination

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[1]Agronomy and Range Science and [2]Seed Biotechnology Center- University of California, Davis, CA; Forage Genetics International, [3]Prior Lake, MN and [4]West Salem, WI; and, [5]Monsanto Company, St. Louis, MO

Out crossing rate, gene flow and pollinator behavior are very important to proper management of commercial alfalfa (*Medicago sativa* L.) seed production. Recent advances in genetic technology have offered new tools to better understand the dynamics of pollinator-mediated gene flow. Studies by Forage Genetics (2002) and St. Amand *et al.* (2000) have previously used genetically-marked pollen to study alfalfa gene flow with alfalfa leaf cutter bee

(*Megachile rotundata* F.), or honey bee (*Apis mellifera* L.) pollination, respectively. The objective of the present study was to measure gene flow using honey bee pollination under commercial seed production conditions in the San Joaquin Valley of California.

This initial study was established in Kings County, California in 2002, and isolated from other alfalfa seed production by at least 6.2 mi (10 km). The Roundup Ready® trait conferring Roundup® herbicide tolerance was used as a pollen-marking tool as follows. A single, 6 A Roundup Ready alfalfa pollen source plot was established in the center of the study area (i.e., the genetically-marked pollen source plot) and eleven, conventional (non-marked) alfalfa pollen trap plots (0.54 A/plot) were established at intervals extending West and East of the source (Fig. 1). All isolation distances were bridged by intervening trap plots, except the shortest distance of 900 ft. At seed harvest (2003), a total of 25 samples were taken in a grid pattern from each trap. Seed samples were planted in a Roundup-treated field evaluation wherein the frequency of gene flow was estimated by counting the percentage of Roundup tolerant seedlings; in all, 75,000 to 90,000 seedlings were tested per trap plot. The study was conducted as permitted under USDA-APHIS notification and State regulations.

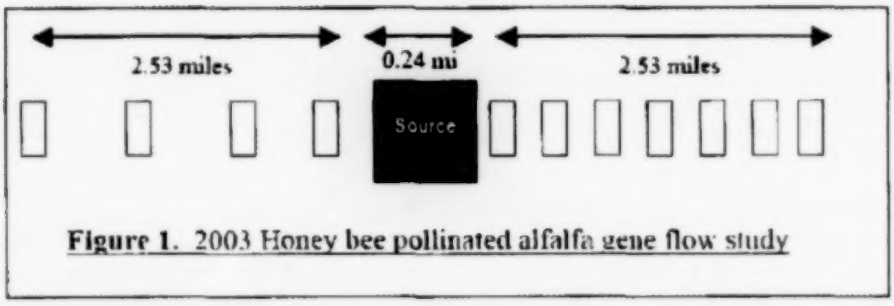

Figure 1. 2003 Honey bee pollinated alfalfa gene flow study

A significant decrease in gene flow with increasing distance from the source plot was observed (Fig. 2). At 900 ft, honey bee-mediated gene flow was 1.49% and it decreased linearly to 0.20% near 5,000 ft. Gene flow continued to decline out to 2.53 miles where it was detected at a low frequency (≤0.06%). Gene flow to the West and the East was not significantly different. These initial, preliminary data will be combined with data from future honey bee pollinated field studies to inform seed production management recommendations so that seed producers may achieve specific seed quality goals.

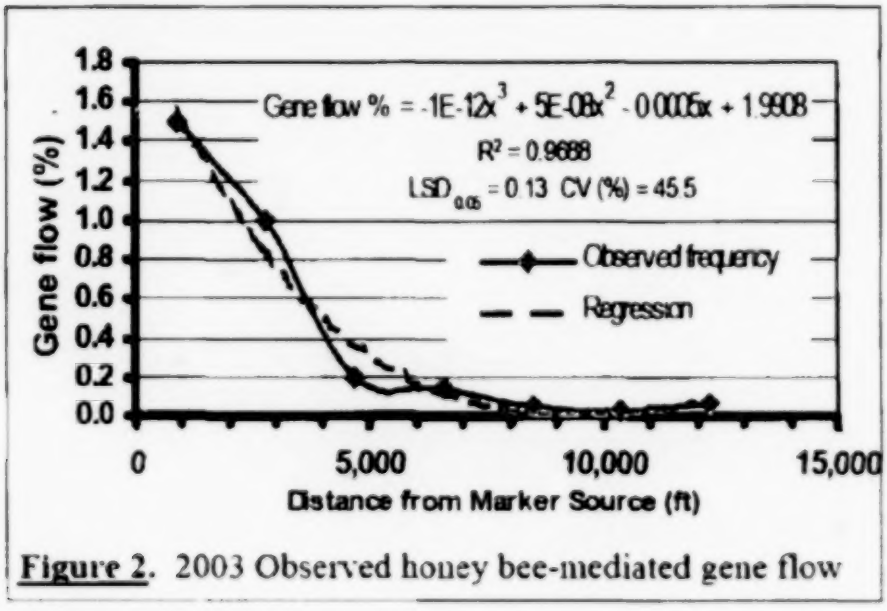

Figure 2. 2003 Observed honey bee-mediated gene flow

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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA – SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants.	NO.: C 06-01075 CRB THIRD DECLARATION MARK H. MCCASLIN Judge: The Honorable Charles R. Breyer

I, Mark H. McCaslin, declare:

1. I am the cofounder and current president and research director of Forage Genetics, Inc., ("FGI"), doing business as Forage Genetics International, a wholly owned subsidiary of Research Seeds, Inc., which is a wholly owned subsidiary of Land O'Lakes, Inc. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto. I previously offered two declarations in support of FGI's motion to intervene and included a current statement of my education and experience.

2. The purpose of this of this Declaration is to clarify the extent of harm that would be caused by any order prohibiting planting of Roundup Ready seed during the next 60-90 days.

3. To frame this discussion, I need to distinguish between the Roundup Ready seed producers and the

approximately 4000 new forage growers who plan to plant this spring season. As I have indicated before, FGI will not enter any new seed production contracts between now and August 2007.

4. The retail value of RRA seed in the commercial pipeline, and destined for spring planting, is about $35M. The following table summarizes the current location of Roundup Ready alfalfa seed in the pipeline for spring planting.

Supply chain	Seed Value
In the ground	$10M
Grower	$10M
Dealer/Distributor	$8M
Seed company	$7M
FGI	0

For the 4000 new forage producers, I estimate that approximately 40% of these farmers have already purchased the Roundup Ready alfalfa seed but have not yet planted. There is no recourse for those who have sold or purchased seed in reliance on the USDA's approval of Roundup Ready alfalfa. There is no legal or contract basis for return or refund for seed in the channel. Seed company return policies routinely provide for return and refund where the seed does not meet widely recognized quality specifications (e.g. germination and varietal purity). All of the Roundup Ready alfalfa seed in the channel meets specification and was and is legal to produce, sell and plant. There will be inevitable direct losses to farmers, small

business owners (dealer and distributors) and seed companies that would result from a 60-90 day prohibition against planting RRA seed. The three quarters of the $35 million dollars in seed that is not yet planted are sunk costs for growers who can not plant it, and for seed companies and dealers who are relying on sales for current income.

5. If the Court orders forage growers to stop planting Roundup Ready alfalfa seed now, the primary growers who will be harmed are those who pose no risk for movement of the transgenic trait—much of the forage to be planted for the remainder of the season is in areas where there is no seed production (i.e. the hay to hay bucket) presents no risk of pollen movement. Based on the vagaries and misfortune of timing or where they live, some growers in critical geographies that depend on high quality hay for dairy producers will be denied the ability to carry out their cropping plan, and will likely not be able to meet the feed needs for their dairy or business obligations to hay-buying dairy customers.

6. Not only will growers be left with seed that they can not plant, but many seed dealers and distributors will not be able to engage in the business that is the source of their livelihood (see Sharp declaration). These are often small and family owned businesses.

7. There is not sufficient seed that will produce like quality hay available to replace the Roundup Ready alfalfa seed that could not be used if the court prohibits planting.

8. Growers plan their crops in reliance on the variety and quality of hay that they will be able to

produce. Many growers produce on contract to meet quality specifications. Planting lower quality seed will not only result in losses of approximately $100.00 per acre in the value of the crop, but will likely result in the inability to fulfill contract obligations. The loss of quality hay production alone over the 225,000 acres yet to be planted would be $22.5 million. In addition, such an order would condemn those growers to produce that lower quality hay for the 5 to 8 year life of their alfalfa stand, resulting in losses from the degraded quality of alfalfa production for the affected growers of more than $112.5 million.

9. About 75% of the acres to be planted this spring will occur outside of the 8 states where 95% of the alfalfa seed production takes place. The Putnam Coexistence paper summarizes his analysis for finding that is nil opportunity for gene transfer from a Roundup Ready alfalfa hay field to a conventional hay field. *See* Exhibit B to Pierson Declaration. We believe that continued planting of RRA seed can occur in this region without any risk of gene flow. In the 8 states where seed production takes place, the standard alfalfa management practice of cutting before first flower should be mandatory and will effectively eliminate any potential risk of gene flow.

10. Our preferred solution continues to be the proposed orders filed by both Intervenors and the Government are different in several respects, but are not complex or difficult to administer. Both seed growers and forage farmers understand the nature of the restrictions in those orders and would be able to follow them. Indeed, both of the proposed orders would minimize any existing potential for contamination of any non Roundup Ready alfalfa crop.

Both thus present an appropriate balance of harms to address plaintiffs' concerns while limiting the damage to farmers. Note that the balance here is between real and immediate harm to thousands of farmers against the hypothetical potential to damage organic and other conventional growers.

I declare under penalty of perjury under the laws of the State of California and the United States of America, that the foregoing is true and correct. Executed this 8th day of March, 2007 at Prior Lake, MN.

s/Mark H. McCaslin
MARK H. MCCASLIN, Ph.D.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE CHARLES R. BREYER

GEERTSON SEED FARMS, et al.	)
Plaintiffs,	)
vs.	) No. C 06-1075 CRB
MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al.,	)
Defendants.	)

San Francisco, California
Thursday, March 8, 2007

REPORTER'S TRANSCRIPT OF PROCEEDINGS

* * *

[5] So let's address that issue first. My inclination would be to permit all three intervenors to intervene, unless there is some strong reason not to.

I think it's discretionary with the Court, but I think they demonstrate a real interest that they should be permitted to intervene. And that will be the order of the Court. So they are now appropriately before the Court in that posture.

That being said, I think that I'm not prepared to address the issue of final relief in the case because I think I have to hear from them. And I—I would think that simply allowing them to intervene and then coming to a final judgment within the same breath doesn't really address the merits of their position.

So I think, really, what I wanted to devote this session to is the question of what I would consider preliminary relief. That is, what relief should I enter between now and some date in the future, to ensure that, one, that the Court's [6] order is carried out in the memorandum and decision or the memorandum and order—what was it called—memorandum and order, and then set a date for some further presentation as what should the final judgment look like.

Yes.

MR. ROSTOV: Your Honor, could I address the intervention issue?

* * *

[8] THE COURT: Okay. So there we are.

Let me tell you what would be useful in the time that we have available. Would be to educate the Court, I think, better than the Court has been educated, as to the status quo as it exists relating to the production of the genetic alfalfa, the growers, where the seeds are, where the plants are, what stage it's all in.

In other words, I'm going to try to fashion some relief. And I don't find the government's submission helpful because I think it is—I don't think it actually addresses the thrust of the memorandum. I'm going to try to stop the proliferation of genetically engineered

alfalfa, pending a further—pending a study, as I've directed.

But when one does that, one has to be mindful of how it would be enforced, what practical effect any order would have, how you would have compliance, what would be the economic burden of any compliance. Those are all issues that I think I need some guidance on.

And I would invite the parties to tell me, what is the status quo? What exists out there in terms of production, in terms of the genetically engineered alfalfa? Where is it? And this isn't, in a sense, a merit-based argument. It's simply this is what's happened, this is the snapshot, this is the way things look out there.

I am in a courtroom. There are no windows. Even if

* * *

[12] arguments can be made. So I'm not foreclosing you from making the arguments, but I want to know exactly what we're talking about.

One is, you are saying FGI, and I assume any other party that—I don't know if there are other entities out there that also produce or sell these seeds. I don't know. If there are, I have to deal with that. But at least one is before me now. You say they won't sell any more of these seeds. Okay. But, of course, they have already sold seeds. Now the question is, what do we do about that? What is the stage of that? And you're telling me, well, they sold seeds to X number of customers; and as to Y number of customers, they've actually planted the seeds.

So I would have to have some idea as to what are we talking about in terms of X, what's that number? What are we talking about in terms of Y?

And, also, are we talking about something that can be done with or should be done with the plants already in the ground? What's the practical implications of that? Or are we talking about orders going out to all of FGI's customers saying, you bought our seeds, don't plant them? Are we talking about that?

Those are the sorts of things that I need to have some advice on, some guidance.

MR. BROWN: I can appreciate that, Your Honor. And [13] Mr. McCaslin is here today, if that would in any way be--

THE COURT: I will listen to anybody who's—you know, anybody that you suggest that I should hear on the subject, I will be glad to hear them.

MR. BROWN: I believe from him you would get it firsthand, Your Honor—

THE COURT: That's fine.

MR. BROWN: —in terms of some of the particular issues that you just addressed.

But in a general fashion, what I can tell you is that in the normal course there is a limit with each of these respective seasons, in terms of how long the seed can be planted.

And because we are coming to the close of that season, we do think that there's very little chance that any additional seed planting would be done prior to August of this year, in the ordinary course and given the action that's been taken by FGI that I mentioned just a moment ago.

I think the other thing that I would just like to call the Court's attention to, Your Honor, is that in the joint intervenors' proposed relief we did try to address this issue, anticipating that there would have to be some need for interim relief before the Court decided what it might want to do on a permanent basis.

And the recommendation that we've made there is that [14] we can fashion a series of measures that are science based and that are field tested, that the Court can rely upon to allow the concerns that specifically this Court raised in its February 13th order would be addressed while further proceedings took place.

THE COURT: Is FGI the only purveyor—do you buy the seeds from Monsanto? How does this work? Tell me how the business works.

MR. BROWN: Your Honor, if I could, I would like to ask if Mr. McCaslin can come forward.

THE COURT: Sure. Come on up. Okay.

MR. McCASLIN: Hi.

THE COURT: Good morning. You are?

MR. McCASLIN: Mark McCaslin. I am the president of Forage Genetics.

THE COURT: Okay. Of FGI?

MR. McCASLIN: Of FGI, correct.

THE COURT: Right. Okay.

MR. McCASLIN: So FGI is a breeding and seed production company. So we don't sell seed to farmers. We develop. It's a product development company. And we also are a seed producer.

So Monsanto has licensed Forage Genetics to develop products and produce seed of Roundup Ready alfalfa. So we are the exclusive licensee.

* * *

[27] So I think that there's a science-based rationale for coming to a conclusion about what should be required to mitigate pollen flow in terms of harvesting the hay and distance from the nearest seed field.

THE COURT: What if the Court entered an order which said all farmers who had genetically engineered seed must harvest—and I don't know that I have the authority to do it; I mean, I'm just trying to figure out ways to deal with it if I could—must harvest their crop before bloom? Let's say I entered some order that said that, and I could enforce it.

What would be the impact of that?

MR. McCASLIN: In the midwest where there is no seed production, that would be a disaster because there's—the challenge in the midwest is usually harvesting around the weather.

In the west—

THE COURT: Harvesting around the weather?

MR. McCASLIN: Right. So you know what mid summer is like in the San Joaquin Valley. There is no—it's all irrigated. You don't have to worry about rain. You can manage harvest. You harvest when you want.

In the midwest the weather is unpredictable, and so alfalfa— the grower might say, my intent is to harvest on Tuesday—

THE COURT: And then a rain comes.

[28] MR. McCASLIN: Then a rain comes, and it happens to turn into Thursday or Friday, or something like that.

So I think such an order in the midwest would be overreaching, you know—

THE COURT: It would be impractical?

MR. McCASLIN: It would be impractical. And, also, there is nil opportunity for pollen flow from hay to hay.

I think to focus—so the way we've looked at it is how do we mitigate—what can we do to mitigate the potential for gene flow where there is seed production? Which is, I think, at least in our mind, is kind of where we focused all of our attention.

THE COURT: And that can be done—

MR. McCASLIN: Combination of enforced harvest, at a certain stage, and when the—when the hay production is within a certain distance of seed production.

And what that distance—what that distance needs to be and what stage you need to harvest, I think there's a lot of scientific studies to actually make a science-based decision in terms of what that should be.

THE COURT: Is this in your proposed—did you submit—I haven't read it yet, so I don't know.

MR. McCASLIN: Actually, the one that presents this in the most detail is Hoffman's second declaration. So it's—you'll see it in our papers, but he actually does a pretty [29] exhaustive analysis of kind of the scientific data behind what their recommendation is. And he cites all of the relevant scientific studies.

THE COURT: I'm particularly interested in the—I understand that his reasons are there. But I'm particularly interested in reviewing the language of the relief, because at the end of the day, that's about where I—that's what I have to do.

Obviously, I'll hear from the plaintiffs on these issues, but you're telling me to go look at that. And maybe I have to ask counsel, is that where I'm going to find this delineation as to what I can do or what I should do, and what I shouldn't do?

MR. BROWN: Your Honor, if this would be an appropriate time to turn to that and to the proposed order that the intervenors have brought forward—

THE COURT: Do you have an extra copy of it?

MR. BROWN: I'm sure we do. Although, I need to find one without notes, Your Honor. Just a moment.

THE COURT: All right.

MR. ROSTOV: Your Honor.

THE COURT: Yes.

MR. ROSTOV: Do I have the opportunity to ask Mr. McCaslin a couple of questions?

THE COURT: Sure. Well, why don't we take a moment. [30] Or why don't you come on up, and if you want to comment on what he has just told me, you can do that. I don't know that we want to turn this into an examination/cross examination.

MR. PAGE: Your Honor, may the government respond after plaintiff questions?

THE COURT: Sure. Everybody can respond.

MR. ROSTOV: Maybe it's not questions, Your Honor.

THE COURT: Sorry?

MR. ROSTOV: I could have questions or I could point to a couple of places in his declaration.

THE COURT: However you want to proceed. What are your concerns about what he just said?

MR. ROSTOV: My first concern is about the planting season, Your Honor. We have declarations that say the planting season starts real soon, March 15th, middle of March. And Mr. McCaslin—

THE COURT: We're talking about the—as I understand, there are basically two planting seasons: One that's already underway, though at various stages, and one that wili commence in August?

MR. ROSTOV: Well, that's my question, Your Honor. Because our point is, the spring planting season in the Pacific northwest starts almost immediately.

And I think Mr. McCaslin is confusing two planting seasons. If you look at his declaration, for example, he's

* * *

[35] don't know that it's of no concern to me, because I have enough concern to think that—that the disruption, in terms of the economic wherewithal of farmers, is of some—it ought to be factored in in some way.

I mean, you're realistic enough to say if there's been planting, there will be the plants. Okay. Now, we are not telling them to pull it out of the ground.

MR. ROSTOV: Correct.

THE COURT: But you're telling them don't plant if you haven't planted. Okay. So that recognizes maybe the practical effect of—you know, of the situation. But now I need to have a better idea of what is the practical effect of telling farmers not to plant?

If I have my druthers, of course, I would tell them, in light of my opinion—in light of my opinion, I would have them go out and pull out all their plants. But I'm

not going to do that, because that's not practical. May not be fair and may not ultimate—ultimately, it may not be warranted. I don't know.

But I've got to come up with a practical short-term solution now. And the question is whether if I simply tell these farmers or have the government tell these farmers, don't plant the seed, just as they did in the rice, don't plant the seed, what then? What then? Does it have a real impact? Is it serious? Is it not so serious? That's what I need to know.

* * *

[48] plaintiffs' decision to not request injunctive relief is, as the Court knows, there has already been a 2006 planting season. Have plaintiffs come running to the Court and asked for an injunction because of irreparable environmental harm during 2006? No. The reason is they can't show any.

So the reason why we would suggest the Haughn and Glickman cases is that the Ninth Circuit praised remedial strategies by a Federal District Court in a situation exactly like this.

When the Court, after reviewing the government's proposed interim regulation, decided to allow science-based interim regulation during the pendency of a Court-ordered NEPA document for equitable reasons, placing the Court in a middle ground between shutting everything down while the federal government diligently completes this EIS, which has changed the culture of the agency, and—

THE COURT: Listen, I'm going to give you as much time as you want to do your EIS, because it's—because Roundup Ready is regulated, as far as I'm

concerned. And so I'm not imposing any time limits or even suggestions. That's up to you. Do it quickly; take your time. You know, that's not a problem. That's not a problem.

But I think in a way I'm sort of getting ahead of myself because I really want to just talk about—and I appreciate what you're saying. You're saying there is a **[49]** regulatory—there is a structure that I could take advantage of, which the government has suggested—after all, you're certainly the interested party here—for minimizing or, in your view, since you don't even think there is any harm, in your view eliminating entirely the possibility or the prospect of any harm. You say that's what we can do. We can effectuate it and there are seven things or there's six things that are listed in the declaration; we'll be delighted to follow those. That's what you're saying.

MR. PAGE: Well, your Honor, yes, with this caveat. We do not want the Court to think or conclude that we have not accepted the Court's view that there is a significant environmental effect under NEPA, because of the possibility of reproduction between engineered and non-engineered.

I think the reason why the government is now saying there is no irreparable harm is, Dr. Hoffman and his team, obviously, read this decision in detail. And the six mandatory regulatory conditions that would be imposed by administrative order are targeted to that gene transfer; and based on the most recent scientific studies, have regulated it to a point of insignificance.

THE COURT: I'm pleased that you've come around to my position.

MR. PAGE: Your Honor, it needs to be said that we're serious about accepting it.

* * *

[57] contract, no, we don't.

THE COURT: Okay.

MR. BROWN: So, Your Honor, I think there is a risk to the growers. We have a hard time quantifying it, but we do state in McCaslin's declaration that one of the economic harms is going to be the lower yield that they're probably going to have with their crop. And we have been able to quantify that. That runs—

THE COURT: That doesn't even make sense to me. Because something may be dangerous, which would have generated a higher yield, and I tell them they can't use it because it's dangerous, if I do say that, then they say, oh, we're harmed because we can't do the dangerous thing which would have produced more of the dangerous thing. I mean, I don't even understand that argument.

Because it seems to me you're arguing—and I'm not faulting you for it, but you're giving me a merit-based argument. You're saying: We just think you're wrong, Judge.

That's what underlies it. Which is okay. Of course you think I'm wrong. You wouldn't be here if you thought I was right.

So the arguments that it's wrong doesn't resonate with me. I need to know—I mean, I have this figure of 35 million. I have no idea what that is. The government was very candid saying to me, well, that may be the costs of, I [58] don't know, the research, or

what went into it, and so forth and so on. But I don't know, you know, what we're really talking about.

By the way, this is a perineal crop, right? So I'm a little unclear as to what the reliance is. The people who we're talking about are new planters, isn't that right, or planting in addition to what they planted before? What is their reliance? Well, they don't have a crop because they are expanding their production.

So, I mean, yeah, I bought something new, and now I can't drive it. Yeah, that's the way life is in the real world. Sometimes the threatened harm makes it difficult for you to do that which you intend to do.

But reliance is a different—you know, when you're relying on something in the future, I don't know. I'm telling them to the extent they've relied on it in the past, that is, they have it in the ground, go for it. I mean, I'm not telling them to do anything different with it.

MR. BROWN: Your Honor, I think what has happened is the reality is, a substantial business has grown out of the decision which was made by the Department back in June 2005, and went commercial in August of that year. It's a business in which my client, FGI, has invested $8 million.

THE COURT: Okay.

MR. BROWN: The $35 million, Your Honor, represents

* * *

[69] MS. SCHNEIDER: : Thank you.

MR. BROWN: Your Honor, could I approach?

THE COURT: Sure.

MR. BROWN: I would like to propose to the Court, if it would be helpful, that the intervenors and perhaps the other parties would be prepared to make a supplemental filing on your question about what would be the harm, the practical effect, if that would be allowed.

THE COURT: I'll entertain it. But you should do it immediately.

MR. BROWN: Okay. Thank you, Your Honor.

THE COURT: Thank you, very much.

Anything further?

MR. PAGE: May I approach, Your Honor?

THE COURT: Yes, briefly.

MR. PAGE: The Court asked questions about the Clear Field rice situation. Is it interested in how the government identified the producers?

THE COURT: Well, I see how the government responded with immediacy. I looked at that situation and thought that, well—and there may be—by the way, the justifications are probably entirely different from any justification here. So I understand that the remedy may have been warranted by the perception of the harm, but there was a remedy saying to farmers: Don't plant. You have it. Don't plant.

* * *

THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC., and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB DIRECT TESTIMONY OF DAN UNDERSANDER REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. My name is Dan Undersander. My business address is University of Wisconsin, College of Agricultural and Life Sciences, Department of Agronomy, 1575 Linden Drive, Madison, Wisconsin 53706.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am a Professor of Agronomy at the University of Wisconsin.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I am an agronomist with a Ph.D. in Agronomy, with over thirty years experience in the field of alfalfa forage production. As discussed below, I was part of the first team of university scientists to evaluate the Roundup Ready alfalfa technology in 2000.

I am currently the co-leader of Wisconsin Team Forage, a team of forage specialists and county agents from across the state responsible for developing and disseminating research-based forage crop information for farmers, agricultural professionals, and educators. I am a member of the board of the NIRS Forage Testing Consortium; a board member and Chair of the Publications Committee of the National Alfalfa and Forage Alliance; a member of the Financial Committee and the Chair of a committee to develop standards for variety testing of the National Alfalfa Improvement Conference; the past Chair of the Forage and Grazinglands section of the Crop Science Society of America; a past Chair of the Computer Software Section of the American Society of Agronomy; and a past member of the board and state representative of the American Forage and Grassland Council. I am also closely involved with the Midwest Forage Association, meeting with the board of directors four times

annually, and am on the advisory boards of five regionally and nationally distributed farming magazines.

I have published numerous books, articles, and extension bulletins/fact sheets relating to alfalfa forage and have produced nineteen websites devoted to the topic. In particular, I organized and edited the Alfalfa Management Guide, which has sold over 300,000 copies and has done much to improve the uniformity and quality of alfalfa production. I led the development and implementation of the Milk per acre spreadsheet, which has become the most widely accepted approach across North America for combining forage yield and quality into a single term to compare forage varieties. I have worked to establish various other programs and tools that are used widely throughout the industry, including "A Guide to Pasture Condition Scoring," a principle tool in identifying compliance with National Resources Conversation Service's CSP Program; the Scissors-Clip Program, a program to provide rapid forage quality analyses to farmers; and the Relative Forage Quality index, a new index for forage quality that has been widely accepted by the forage industry.

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. My testimony will focus on issues of gene transfer, weed control, and weed resistance to herbicides, particularly as they relate to Roundup Ready alfalfa in the eastern half of the United States.

II. ALFALFA HAY PRODUCTION AND GENE FLOW

Q. PLEASE DESCRIBE THE ALFALFA PRODUCTION IN THE EASTERN UNITED STATES.

A. For the purposes of this discussion, I am defining the eastern United States as the area east of the Missouri River. Alfalfa production in this region is strictly for forage (e.g. hay and haylage, which is fermented as opposed to dry hay); *there is no significant alfalfa seed production in the eastern United States.* Alfalfa forage in the region is primarily fed to dairy cows, with a smaller amount fed to beef cows and horses. Approximately 80% of the hay/haylage harvested in the region is fed on the farm where it is grown, the remainder is sold as a cash crop. Alfalfa hay/haylage is harvested 2-5 times per season in the region. Forage quality declines rapidly after first flower and harvest timing is driven by forage quality. Organic alfalfa accounts for less than 0.5% of the total acreage in the region.

Q. IN YOUR OPINION, IS GENE TRANSFER FROM ROUNDUP READY ALFALFA HAY TO ORGANIC OR CONVENTIONAL ALFALFA HAY LIKELY?

A. I believe such gene transfer is extremely unlikely. The combination of timing of cutting, the lack of pollinators, and the fact that no natural reseeding occurs in an alfalfa stand due to autotoxicity and other reasons, makes the risk of hay to hay gene transfer negligible.

III. WEED CONTROL

Q. IS WEED CONTROL A SIGNIFICANT ISSUE FOR ALFALFA GROWERS?

A. Effective weed control is critical during stand establishment. Weed competition during the first 60 days after seeding can significantly reduce alfalfa stand density and yield in subsequent years. Winter annual weeds can reduce stand life, are difficult to control, and a common problem in much of the region. Perennial grass weeds (e.g. quackgrass) are common in the later years of a stand, are difficult to control and can have a significant impact on forage quality.

Q. HOW DO ALFALFA GROWERS MANAGE WEED GROWTH?

A. Cover crops have traditionally been used to help control weeds during stand establishment, but this method is declining rapidly because of decreased demand for the straw harvested from the cover crop, and the reduction in alfalfa yield caused by the cover crop competition. Post emergence herbicides are now widely used for weed control in establishment. Often a "cocktail" of two herbicides is required to control all of the potential broadleaf and grass weed problems. As mentioned above winter annual and perennial weeds in established stands are difficult to control with conventional herbicides.

Q. ARE YOU FAMILIAR WITH THE ROUNDUP READY ALFALFA PRODUCT?

A. Yes. In 2000, I was part of the first team of university scientists to evaluate the technology. I have conducted several experiments since then to

evaluate the technology in comparison with conventional herbicides and/or to evaluate Roundup Ready alfalfa varieties versus conventional cultivars.

Q. IN YOUR OPINION, IS ROUNDUP READY ALFALFA AN EFFECTIVE PRODUCT TO CONTROL WEEDS?

A. Yes. The Roundup Ready system provides broad spectrum weed control, offering a new opportunity to control problem weeds. It also has excellent crop safety, and offers growers increased flexibility in timing of application.

Q. DOES ROUNDUP READY ALFALFA HAVE ANY OTHER BENEFICIAL QUALITIES?

A. In our trials, the Roundup Ready alfalfa varieties have performed as well as the best conventional varieties on the market. The excellent pest resistance, winterhardiness and forage yield potential of these varieties enhance the value of the Roundup Ready technology.

IV. WEED RESISTANCE

Q. WHAT IS WEED RESISTANCE AND HOW DOES IT DEVELOP?

A. There is a natural process in antibiosis for target organisms to develop resistance to plant resistance genes and specific pesticides. For example, plant pathogens "evolve" to overcome specific plant disease resistance genes, insects develop strategies for overcoming plant resistance genes and develop resistance to specific insecticides and weeds develop resistance to specific herbicides. Integrated pest management strategies that engage multiple control strategies have been

successfully employed to manage the development of this type of resistance.

Q. HAVE YOU READ THE COURT'S FEBRUARY 13, 2007 ORDER IN THIS CASE?

A. Yes.

Q. IN ITS FEBRUARY 13 ORDER, THE COURT EXPRESSED CONCERN THAT THE USE OF ROUNDUP READY ALFALFA COULD CREATE GLYPHOSATE-RESISTANT WEEDS. DO YOU HAVE AN OPINION ABOUT WHETHER THE USE OF ROUNDUP READY ALFALFA WILL CREATE GLYPHOSATE-RESISTANT WEEDS?

A. The development of herbicide resistant weeds requires that the weeds are allowed to produce seed for multiple generations in a field that has a single herbicide applied year after year. Because alfalfa is cut multiple times during the season, most weeds are cut along with the alfalfa before they are able to produce seed. Furthermore, our trials show that only one or two applications of Roundup are required during the entire 4-5 year Roundup Ready alfalfa rotation in our region. For these reasons, I believe that Roundup Ready alfalfa is an unlikely source for the development of glyphosate resistant weeds.

Q. IN YOUR OPINION, WILL THE USE OF ROUNDUP READY ALFALFA CREATE GLYPHOSATE RESISTANT WEEDS, PARTICULARLY IN CONJUNCTION WITH THE USE OF OTHER ROUNDUP READY CROPS?

A. I do not see Roundup Ready alfalfa as a likely source of glyphosate-resistant weeds. Many Midwest growers are rotating Roundup Ready alfalfa with their Roundup Ready corn and soybean crops *as a method for managing weed resistance in those crops.* Because alfalfa is repeatedly clipped during the growing season, weeds cannot produce seeds. Consequently, the repeated cycle of herbicide application coupled with weed seed production is broken and prevents the development of glyphosate-resistant weeds.

Q. WHAT ARE THE ACTIONS GROWERS CAN TAKE TO MINIMIZE THE RISK OF WEED RESISTANCE?

A. Growers should use an integrated strategy that includes using multiple herbicides in rotation and harvesting alfalfa before weeds can produce seed.

Q. IS THE USE OF ROUNDUP READY ALFALFA DURING THE NEXT TWO TO THREE YEARS, DURING THE TIME WHEN AN ENVIRONMENTAL IMPACT STATEMENT IS BEING PREPARED, LIKELY TO CREATE OR CONTRIBUTE TO THE DEVELOPMENT OF GLYPHOSATE-RESISTANT WEEDS?

A. No, the evolution of weed resistance takes a number of years. Weeds would not develop a resistance to glyphosate in two to three years. Additionally, if a grower uses an integrated herbicide strategy, cuts alfalfa hay before weeds can produce seed, and treats potential weed escapes, these practices will prevent the development of glyphosate-resistant weeds. There

are no known glyphosate-resistant weeds that occur in alfalfa.

Q. IS THE RISK OF WEED RESISTANCE ASSOCIATED WITH THE USE OF ROUNDUP READY ALFALFA GREATER THAN THE RISK OF WEED RESISTANCE ASSOCIATED WITH THE USE OF OTHER HERBICIDES?

A. No, the biological process for development of resistance is the same. In fact, resistance to Roundup is not as common as resistance to many other herbicides.

Q. DOES THIS CONCLUDE YOUR TESTIMONY?

A. Yes, it does.

Thank you.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 23 day of March 2007 at 7 a.m.

/s/
DAN UNDERSANDER

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby atteset that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/
B. ANDREW BROWN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor- Defendants.	No. C-06-01075 CRB DIRECT TESTIMONY OF LARRY R. TUEBER REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. Larry R. Teuber, Department of Plant Sciences, Mail Stop 1, One Shields Ave., University of California, Davis, California 95616-8780.

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am Professor of Plant Sciences, Director of the University of California Foundation Seed Program (FSP), and Executive Director of the California Crop Improvement Association (CCIA). The FSP receives seed from University of California plant breeders (breeder seed) when a new variety is released, and is responsible for the increase, maintenance of genetic purity, and distribution of foundation seed for the life of the variety. The CCIA is a non-profit corporation that is housed at the University of California, Davis, and that is officially recognized as California's seed certifying agency under the California Seed Law. The mission of the CCIA is to provide services and support research that promotes the improvement, production, distribution and use of superior quality seeds and other agricultural products. The CCIA certifies the seed production of both conventional and genetically engineered cultivars of over forty different crop species grown on more than 150,000 acres in California. We are the official state designated certification agency for potato seed (tubers) and a National Organic Program (NOP) accredited organic certifier.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I received my Ph.D. in Plant Breeding and Genetics from the University of Minnesota in 1978. For the past 35 years, I have conduced research related to alfalfa pollination and seed production. My research investigations have included factors influencing pollinator behavior (such as nectar production, aroma, and the tripping mechanism), seed production practices, and out-crossing rates.

In recent years, my research has focused on pollen mediated gene flow and the development of genetic resistance to insects including the Lygus bug, which is the most serious insect pest affecting alfalfa seed production. I was the first to release a cultivar, from any species, with resistance to the silverleaf whitefly. I am the author or coauthor of over 150 peer review and extension papers, and book chapters on alfalfa breeding and production. I teach Forage Crop Production, Introductory Statistics, Advanced Plant Breeding, and I am one of three Lead Instructors in the University of California, Plant Breeding Academy. I am a member of the USDA-ARS Alfalfa Crop Advisory Committee and have released or co-released four cultivars and over 50 germplasm pools. As a plant breeder and as the director of both the FSP and the CCIA, I have been involved at many different levels in commercial seed production. Currently, I am the chair of the National Alfalfa and Clover Variety Review Board. A copy of my curriculum vitae is attached as Exhibit A.

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. I am testifying about the likelihood of gene flow between Roundup Ready and conventional alfalfa, which was one of the Court's concerns in its February 13, 2007, Memorandum and Order.

II. GENERAL INFORMATION ABOUT ALFALFA

Q. HOW IS ALFALFA POLLINATED?

A. Alfalfa is a perennial, cross-pollinated crop. It has indeterminate flowering and will bloom from as

early as late May to early August under normal seed production practices. Bee pollinators are required to "trip" flowers in order to release and transfer pollen for seed production. Tripping is the forceful release of the anthers (male structure) and the pistal (female structure) which is necessary before pollination can occur. U.S. alfalfa seed producers most frequently use either alfalfa leafcutter bees or honey bees as pollinators. Alfalfa is not wind pollinated.

Q. WHAT IS POLLEN MEDIATED GENE FLOW AND HOW MIGHT IT OCCUR?

A. The only mechanism for effective gene movement from one plant to another is by pollination. Managing pollen mediated gene flow (PGF) is a critical mechanism for maintaining genetic purity during certified seed production of conventional and biotech varieties of all crops. Pollen mediated gene flow in alfalfa could theoretically occur in five different ways: 1) Between a domestic cultivar and feral alfalfa, 2) between a hay production field and a seed field (*HAY* to *SEED*); 3) between two different seed production fields (*SEED* to *SEED*), 4) between a seed production field and a hay production field (*SEED* to *HAY*); and 5) between two different hay production fields (*HAY* to *HAY*). Under hay production practices that prevail in California, I believe both seed to hay and hay to hay transmission are highly unlikely. I would like to focus my discussion on my research on measuring potential pollen mediated gene flow in seed production, both SEED to SEED and HAY to SEED.

III. SEED TO SEED GENE FLOW (BETWEEN SEED PRODUCTION FIELDS)

Q. How are alfalfa seed production fields pollinated?

A. In the United States, alfalfa seed production fields are pollinated with leafcutter bees (*Megachile rotundata* F.) in the Pacific Northwest and primarily by honey bees (*Apis mellifera* L.) in California. A small number of growers in Washington and Nevada use alkali bees (*Nomia melanderi* C.) for pollination. Although viable seed production requires the transfer of pollen from one plant to another, control of pollen movement is important to minimize adventitious presence (AP), the presence of unwanted genes in a crop, and for maintenance of genetic purity during both conventional and transgenic alfalfa seed production. Understanding alfalfa outcrossing rates, gene flow, and pollinator behavior is very important to proper management of commercial alfalfa seed production, regardless of whether the cultivar is conventional or transgenic.

Q. What are the current isolation standards for alfalfa in the United States?

A. One of the most important stewardship measures growers can take to minimize gene flow between alfalfa seed fields is the implementation of isolation distances. Current Association of Official Seed Certifying Agencies (AOSCA) minimal isolation standards for alfalfa in the United States are 165 feet (50 m) from other alfalfa grown to produce certified seed and 900 feet (274 m) for foundation seed production. Certified alfalfa seed is produced

on approximately 26,000 acres in California and is about equally divided between two principal production areas. These are the San Joaquin Valley and the Imperial Valley. Agricultural crops are produced on approximately 3.3 million acres in the 5 major seed producing counties in the San Joaquin Valley. Hay is produced on about 300,000 of these acres. The Imperial Valley produces agricultural crops on about 485,000 acres, of which about 165,000 acres are in alfalfa production. FGI has voluntarily imposed a three mile isolation standard for certified seed production of Roundup Ready alfalfa in California when honeybees are used as the introduced pollinator. This is >90 times what is required for certified seed production of conventional alfalfa. The three-mile isolation distance was adopted as an industry/CCIA consensus and was based on the results from pollen flow experiments that I conducted with UCD colleagues between 2002 and 2005, and the not-detectable AP standard required for specific alfalfa seed export markets. In addition, the stakeholders reached an agreement restricting the use of Roundup Ready alfalfa in the Imperial Valley.

Q. WHAT IS THE BASIS FOR ISOLATION DISTANCES?

A. The current isolation standards for *conventional* alfalfa are based on data collected in the 1980s, which used differentials in pest resistance genes as pollen flow markers between adjacent seed production fields. (Brown et al., *Committee on alfalfa field isolation, Report of the 30th N. Am. Alfalfa Improvement Conference*(1986)). The standard for *conventional* alfalfa was set to achieve 99% or greater genetic purity based on

these studies. More recent studies have used biotech markers to more accurately measure pollen mediated gene flow. (Teuber et. al., *Gene Flow in Alfalfa Under Honey Bee Pollination* (2004), attached as Exhibit B; Teuber et al., *Gene Flow in Alfalfa When Honey Bees are Used as Pollinators* (2005), attached as Exhibit C; Fitzpatrick et al., *Pollen-mediated Gene Flow in Alfalfa: A three year Summary of Field Research* (2003), attached as Exhibit D). The isolation standards currently being used for seed production of Roundup Ready alfalfa are pollinator specific and based on these most recent research studies.

Q. HOW WERE THESE MORE RECENT POLLEN FLOW EXPERIMENTS CONDUCTED?

A. A federally permitted study I conducted in the San Joaquin Valley of California in 2003 measured gene flow using honey bees as pollinators under commercial seed production conditions. The study was designed to determine the extent of gene flow using honey bees in alfalfa on a field plot scale. The Roundup Ready trait conferring Roundup herbicide tolerance was used as a pollen-marking tool as follows: A single, six-acre Roundup Ready alfalfa pollen source plot was established in the center of the study area (i.e., the genetically-marked pollen source plot) and eleven, conventional (non-marked) alfalfa pollen trap plots (0.54 acre/plot) were established at intervals extending West and East of the source. All isolation distances were bridged by intervening trap plots, except the shortest distance of 900 feet. At seed harvest (2003), a total of 25 samples were taken in a systematic grid pattern from each trap.

Seed samples were planted in the field and seedlings were sprayed with Roundup twice at a two-week interval. The total number of seedlings was estimated from representative plant counts and the number of surviving Roundup tolerant seedlings was counted to determine the frequency (percent) of gene flow for each trap plot. In all, 75,000 to 90,000 seedlings were tested per trap plot for a total of 1.2 million seedlings. The study confirmed the presence of the roundup resistant protein (equivalent to gene flow) in surviving seedlings using test strips specific to the Roundup Ready protein.

Q. WILL YOU SUMMARIZE THE RESULTS FROM THIS EXPERIMENT?

A. As in the previously conducted bee mediated pollen flow experiments using leafcutter bees, this honey bee study revealed a significant decrease in gene flow with increasing distance from the source plot. At 900 feet (274 m), pollen-mediated gene flow was less than 1.58 percent, and it decreased to less than 0.2 percent near 5,000 feet (1.5 km). Gene flow continued to decline to a distance of 2.5 miles (4 km), where it was detected at a very low frequency (< 0.03%). The isolation distance required for gene flow to fall below 1% in this honey bee experiment is approximately three times farther than that reported in the leafcutter bee experiments, which helps illustrate the importance of pollinator-specific isolation requirements.

IV. GENE FLOW FROM HAY TO SEED FIELDS

Q. WHAT IS THE POTENTIAL FOR GENE FLOW FROM HAY TO SEED FIELDS?

A. This depends on two key factors, the amount of flowering in the hay production field and the isolation distance between the two fields. As with Seed to Seed pollen flow, Hay to Seed pollen flow decreases exponentially with increased isolation distance.

Q. HOW ARE HAY TO SEED EXPERIMENTS CONDUCTED?

A. I have been conducting research to examine the potential for Hay-to-Seed type of gene flow. Our study is, I believe, only the second study of this type ever conducted and is more comprehensive. The first study was conduced by Forage Genetics International. In both studies, effective gene flow was measured from Roundup Ready hay fields (sources) to conventional seed fields (sinks). These studies used the Roundup Ready trait as a marker tool to easily and accurately measure pollen flow. The Forage Genetics study was conducted in Washington with leafcutter bee pollinators.

My larger hay-to-seed study is being conducted at the University of California, Davis. (See Teuber and Fitzpatrick, Assessment of Alfalfa Gene Flow Between Fields Planted for Hay Production and Adjacent Fields Used for Seed Production (2006), attached as Exhibit E.) This study was initiated in 2005 using honey bees as pollinators on the seed plots. The 1.32 acre (0.53 ha) hay field (source) was planted with a Roundup Ready cultivar. Extending from the hay field in four different

directions are one-third acre (0.13 ha) seed fields planted to a conventional cultivar. The centrally located hay field was harvested on a 30 to 34 day cycle throughout the 2006 production season. This cutting cycle permitted the forage to reach as much as 20% bloom each cutting cycle. The leading edge of each seed field was located at 165 feet from the Roundup Ready hay field and extended for 500 feet. The choice of 165 feet between the hay and seed field in the University of California study was based on the minimal isolation standard required between dissimilar cultivars under the California seed certification standards established by the Association of Official Seed Certifying Agencies (AOSCA). Seed fields began to bloom on June 4, 2006. Honey bees were placed in these fields on June 22 when the seed crop was estimated to be at 80% bloom. When the bees were placed in the seed fields, the hay field was at a pre-bud developmental stage. During pollination the centrally located hay field was harvested on June 28, and again on August 1. At the time of cutting the hay field was at about 20% bloom and seed fields were in full bloom.

Q. WHAT WERE THE RESULTS OF THE STUDY?

A. Although the California study examined gene flow to a greater distance from the source than the earlier leafcutter bee study, first year results from the honey bee study were similar to the results from the earlier leafcutter bee study between 165 and 300 feet from the marker source. Under these conditions, gene flow into the seed field was very low ($\leq 0.25\%$) at 150 and 300 feet, and it was rarely detected (0.00 to 0.05%) at distances greater than

350 feet from the source. These results are consistent with existing standards for certified seed production.

Q. HOW CAN GENE FLOW BE MINIMIZED?

A. Hay to Seed gene flow can be most effectively managed by requiring isolation between Roundup Ready hay production and any nearby conventional seed production. My research indicates that the current isolation requirements for certified seed production are adequate to protect against hay to seed gene flow. Pollen mediated gene flow could be further decreased by requiring greater isolation distances and more aggressive cutting management of the hay field.

V. SUMMARY

Q. WHAT ARE YOUR RECOMMENDATIONS FOR THE SUCCESSFUL MANAGEMENT OF ROUNDUP READY ALFALFA GENE FLOW?

A. Seed producers and regulators recognize that genetic purity of the harvested seed crop is related to physical isolation between the seed field and outside sources of pollen. Research studies have provided important data critical for setting effective isolation standards that preserve specific alfalfa seed markets (Roundup Ready and conventional). I believe we now have the knowledge and the tools required to effectively manage coexistence of seed production serving the various markets where Roundup Ready and conventional alfalfa seed are sold. Although at this time there is no certified organic alfalfa seed production in California, the same tools could be applied to effectively manage this activity.

Q. BASED ON YOUR EXPERTISE, DO YOU THINK IT WOULD BE APPROPRIATE FOR THE COURT TO ALLOW THE PLANTING OF ROUNDUP READY ALFALFA TO CONTINUE WHILE APHIS PREPARES AN ENVIRONMENTAL IMPACT STATEMENT?

A. Yes. We have enough information to safely manage the continued planting of Roundup Ready alfalfa while APHIS prepares an EIS, as long as appropriate stewardship measures are in place. These stewardship measures should include specified isolation distances, harvesting conditions to minimize cross-pollination, equipment cleaning, and requirements for the identification and handling of seed. These stewardship measures are consistent with the stewardship plan that is already in place in California.

Q. DO YOU HAVE ANY FURTHER TESTIMONY?

A. No, that's all.

Thank you.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 23rd day of March 2007 at Davis, California.

/s/

LARRY R. TEUBER, Ph.D.

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/

B. ANDREW BROWN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS INC. *et al.* Plaintiffs, v. ~~MIKE~~ JOHANNS, *et al.* Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE, Intervenor-Defendants.	Case No. C06-1075 CRB SECOND DECLARATION OF LOUIS M.S. MEYER, IN SUPPORT OF MONSANTO COMPANY'S MEMORANDUM ON PROPOSED PERMANENT INJUNCTION Date: April 27, 2007 Time: 11:00 a.m. Place: 19th Floor, Courtroom 8 Judge: Hon. Charles R. Breyer

SECOND DECLARATION OF LOUIS MEYER, IN SUPPORT OF MONSANTO'S MEMORANDUM ON PROPOSED PERMANENT INJUNCTION

I, Louis Meyer, declare as follows:

1. I am the Product Management Lead for Specialty Crops with Monsanto Company ("Monsanto"), a position I have held since 2002.

2. In my capacity within the Product Management group, I have responsibility for specialty crops, which includes Roundup Ready® alfalfa.[1] My responsibilities include working with Forage Genetics International ("FGI"), the company licensed by Monsanto to produce Roundup Ready alfalfa, on certain matters relating to business and industry affairs, market strategy and future technologies. I have previously filed a declaration in this case dated March 2, 2007, that outlines my qualifications and experience in greater detail. I have personal knowledge of the matters referred to herein and if called upon to testify, could and would testify truthfully thereto.

3. As I understand it, the Plaintiffs have asked the Court to prohibit further sales or planting of Roundup Ready alfalfa while the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS") completes further review of the potential environmental effects of deregulating Roundup Ready alfalfa, which could take up to two years. A prohibition of further sales or planting of Roundup Ready over this two year period would harm Monsanto's financial interests and its ability to advance research and development of products that will benefit farmers in the United States and throughout the world.

4. Based on projected sales and the best information that we currently have available, we estimate that, if sales of Roundup Ready alfalfa continue to be limited by court order, Monsanto would

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[1] ® Roundup and Roundup Ready are registered trademarks of Monsanto Technology LLC.

lose a total of roughly $27 million in revenue from technology premiums during 2007 and 2008.

5. If these revenues are lost as a result of a prohibition on further sales of Roundup Ready alfalfa, they will not be available for reinvestment in research and development of products to benefit farmers in the United States and throughout the world. This may have the effect of delaying progress in bringing beneficial new products to market, to the detriment of farmers.

I declare, under penalty of perjury, that the foregoing is true and correct.

Executed this 21st day of March, 2007 in St. Louis, Missouri.

/S/
Louis Meyer, M.S.

Attorney Signature Attestation

I, Holly J. Tate, counsel for Monsanto Company, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature /S/ within this efiled document.

/S/
Holly J. Tate

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF JOHN FENDRYK REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, John Fendryk, declare:

1. I farm 2,500 acres in Beaver, Wisconsin, which is located in Northeast Wisconsin, 50 miles north of Green Bay. We have 530 dairy cows. We have 1,000 acres of corn and 1,000 acres of alfalfa which I grow as feed for my own livestock. I also have 500 acres of beans. I am 55 years old, have farmed all my life and am a third generation farmer. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. I planted 160 acres of RoundUp Ready Alfalfa ("RRA") in April 2006. When I purchased the seed for RRA, I signed the Monsanto/Technology Stewardship

Agreement and was provided with a copy of the Monsanto/Technology Use Guide ("TUG"). I understand the TUG requires harvesting at or before 10% bloom, which is my practice as that is when the alfalfa is at its highest quality.

3. The results with RRA were excellent. The quality was great and the first two cuttings were weed free. I was so pleased with RRA that I was planning on planting an additional 50 acres this spring. I understand that the Court's Preliminary Injunction Order would allow me to plant up until March 30, 2007. While that might work in other parts of the country, there is no way I will be able to plant by March 30 because our ground is still frozen.

4. If allowed to do so, I will ultimately replace all my alfalfa with RRA. RRA is cheaper to grow than conventional alfalfa, RoundUp does not stunt the growth of the alfalfa (as the chemicals used on conventional alfalfa do) and RoundUp is half the cost of the chemicals you have to use with conventional alfalfa. Moreover, RRA results in high quality feed and greater yields—my yields with RRA have been three tons per acre versus the two and a half tons per acre I got with conventional alfalfa that also ends up having a lot of weeds in it.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 20th day of March 2007 at Beaver, Wisconsin.

/s/ John Fendryk
JOHN FENDRYK

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF BRIAN GORDON REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Brian Gordon, declare:

1. I farm 2,500 acres in Alva, Oklahoma. On those acres I grow wheat and alfalfa. I have been farming for 25 years. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. I am currently growing 350 acres of alfalfa, thirty acres of conventional alfalfa and 320 acres of RoundUp Ready alfalfa ("RRA").

3. I planted the conventional alfalfa three years ago but have been unable to control the weeds with the recommended herbicides. Because I cannot control the weeds (primarily Pig Weed and Johnson Grass), I have been unable to sell the hay for more money than it has cost to produce it.

4. In the fall of 2006, I decided ot try RRA because I was told that RRA could control the weeds. I planted 320 acres with RRA and although I have not yet had the first cutting, I can see that the weeds have been controlled. People have called me to purchase my hay at market price, which is anywhere from $125 to $200 per ton depending on how weed free it is and its quality. I sell my alfalfa primarily to dairies and horse operations. My ability to sell to these customers depends on the hay being essentially be weed free. The horse people are particularly picky and will reject hay if it contains any weeds whatsoever.

5. I made the decision in fall 2006 to plant an additional 160 acres of RRA in spring 2007. The court's Preliminary Injunction Order prevents me from planting RRA this spring because, although I could get it planted by the March 30, 2007 deadline, I had not purchased it prior to March 12. Because of the weed issues I face, planting conventional alfalfa simply is not an option and would be a money losing proposition.

6. If I could plant RRA this spring, the first cutting would be harvested in the middle of June, with an expected total of four cuttings this year. Conservatively, I estimate my lost net income to be approximately $64,000.

I declare under penalty of perjury under the laws of the State of California and the United States of

America that the foregoing is true and correct. Executed this 21 day of March 2007 at Alva, Oklahoma.

/s/ Brian Gordon
BRIAN GORDON

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF JOHN GROVER REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, John Grover, declare:

1. I farm 800 acres in Powell, Wyoming. I am an alfalfa seed grower and grow RoundUp Ready alfalfa ("RRA") under contract with Forage Genetics, Inc. ("FGI"). I am an intervenor-defendant in this action and previously submitted a declaration in support of the Motion to Intervene of myself, Daniel Mederos and Mark Watte, a copy of which is attached. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. We have been growing alfalfa seed on our farm for 20 years. Based on the conditions in our area, alfalfa seed is the only crop that I can make money on. While I do raise malt barley, grass for seed and hay, I don't break even on those crops—I grow them primarily as rotational crops between alfalfa seed plantings. Sugar beets and dry beans are grown in this area but are not an option for my farm mainly because of our elevation at 5200 feet, which causes production to suffer, and because the margins on these crops have gotten progressively more narrow.

3. I currently have 204 acres of RRA seed and 325 acres of conventional alfalfa seed. The 325 acres of conventional alfalfa seed is in its last year and those acres will rotate out this year. I will rotate those acres into barley for two years until they can go into alfalfa seed again. I was expecting to be able to plant more RRA seed on those acres but will not be able to do so if the court's Preliminary Injunction Order continues to be in effect. Obviously if I have to keep those acres in barley, my farm will be much less profitable.

4. This spring I had a contract to plant an additional 200 acres of RRA, however I will not be able to do so as a result of the court's preliminary injunction order. The loss of these acres represents a potential loss of income of $20,000. What I will be able to do with those acres is still not certain.

5. I understand the demand for RRA has been high and the expectation was that I would continue to increase my acreage of RRA seed, which will ensure the success of my farm. If the court's Preliminary Injunction Order continues in effect for any period of time I will lose my most valuable crop. While it's

possible that I could grow conventional alfalfa seed, assuming there are contracts for it, that would be a less profitable crop due to increased costs of weed control (RoundUp versus more expensive chemicals), which would obviously affect my bottom line. In addition, the weed control alternatives to RoundUp are not only more expensive, they are also much more toxic.

6. The $20,000 figure listed above is a minimum that I would lose in the establishment year of growing conventional alfalfa, rather than RRA alfalfa. We normally apply four separate herbicides, plus cultivate three times, and still end up with a dirtier field than when we are able to just spray a low dose of RoundUp twice. If we have tough perennial weeds such as sweet clover, in the second year those can only be removed by hand labor (if you can even find labor), and at a great expense I've personally experienced costs of over $90.00 an acre in the second year. With RRA and spraying $12 to $15 worth of RoundUp, the problem is eliminated.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 21st day of March 2007 at Powell, Wyoming.

/s/ John Grover
JOHN GROVER

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF BLAKE HARLAN REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Blake Harlan, declare:

1. I run an 8,000-acre farm in Woodland, California. We grow tomatoes, rice, alfalfa, wheat, sunflowers, safflower seed and corn. I have been farming all my life and our farm has been in our family since 1850. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. One of our largest crops is alfalfa hay. We currently have 1500 total acres planted with alfalfa, 310 of which are planted with RoundUp Ready Alfalfa

("RRA"). We planted approximately 200 acres of RRA in the fall of 2005 and 100 acres in the fall of 2006.

3. I have signed the Monsanto/Technology Stewardship Agreement and I am familiar with the requirements of the Monsanto/Technology Use Guide, including the requirement for harvest at or before 10% bloom. We comply with this requirement since that is when we always harvest our alfalfa to get the highest quality.

4. I have been very pleased with the performance of RRA. My three RRA fields have out yielded all of my conventional fields. While the county average for alfalfa yield is 6 1/2 tons per acre, I have gotten [handwritten: up to bh] 9 1/4 tons per acre from my RRA fields. This performance is particularly phenomenal as my RRA is planted in Class 2 ground. While it is not uncommon to get yields between 9 and 10 tons per acre from alfalfa planted in Class 1 ground (the highest quality soil), such yields in Class 2 ground are outstanding.

5. RRA is a particularly good crop for certain acreage on our farm that has severe weed problems. In Yolo County, all the water we use in our farming operation is surface water that comes from the lake country and picks up a lot of weed seeds as it makes it way to our property. Each time we irrigate brings a fresh weed infestation to our fields. Fields that are prone to flooding have even bigger weed problems. Weeds that are a particular problem on our farm are nut grass and Johnson weed. When such weeds grow in an alfalfa stand, they always detract from the price you can get for your hay—their presence also limits where such hay can be shipped. Planting RRA on such

problem acres allows us to achieve near perfect weed control. This in turn allows us to get maximum production from such acres that we could not get with other crops.

6. Another big advantage that RRA has over conventional alfalfa is the advantage RoundUp has over the herbicides that must be used on conventional alfalfa. With conventional alfalfa, the chemicals are much more expensive ($40 per acre versus $20 per acre for RoundUp), stunt the growth of the seedling alfalfa and they are highly toxic. RoundUp, on the other hand, does not stunt the growth of the seedling alfalfa and is much less toxic.

7. We plan to plant more alfalfa in the fall and if allowed, we will plant RRA. RRA is a great tool for us and one that we would like to have in the future. The benefits are numerous and our entire operation benefits from the clean fields that result from its use. A court order preventing further planting of RRA will deny us those benefits.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 22nd day of March 2007 at Woodland, California.

/s/ Blake Harlan
BLAKE HARLAN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF LINCOLN HUGHES REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Lincoln Hughes, declare:

1. I farm 160 acres in Nevada, Missouri. We are a row crop operation located in Southwest Missouri. I also contract farm 3,000 acres. I am 28 years old and have been farming my entire life. My wife Trinnnade and I have three small boys and our livelihood is dependent on our farming operation, which is basically just getting started. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. Last year we made the decision to plant 370 acres of RoundUp Ready alfalfa ("RRA") in the spring of 2007 because of its ability to control weeds that tend to be a problem in our area and cannot be controlled with traditional chemicals.

3. In reliance on the availability of RRA, we made a number of serious financial commitments. Specifically, we entered into a six-year contract with a dairy to provide weed free hay. We also purchased equipment specifically to harvest this new RRA crop in the amount of $164,000, including a mower, a rake and a Peterbilt truck to transport the hay. We had to borrow money in order to make these purchases.

4. The court's Preliminary Injunction Order prevents us from performing our contract and leaves us with expensive equipment that we otherwise would not have purchased. Although I understand that the court's order would allow us to plant if we could do so by March 30, 2007, that simply is not possible due to weather conditions in our area. I conservatively estimate that our lost hay production revenue for the next two years will be in the neighborhood of $330,000. Our inability to perform our contract hurts our reputation and could result in the loss of future contracts with other dairies. Without our RRA crop, we will also be forced to find other means of income in order to pay the debt on the new equipment that we have purchased.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 21 day of March 2007 at Nevada, Missouri.

s/ Lincoln Hughes

LINCOLN HUGHES

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF JOE MARACHETTI REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Joe Marchetti, declare:

1. I have a 75-acre farm in Bakersfield, California. Our principal business is raising dairy heifers and we have anywhere from 200 to 400 head at any given time. Our farm has been in my family since 1919. I am 66 years old, drove my first tractor when I was 6 years old and have been raising heifers since 1958. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. We have approximately 60 acres devoted to forage to feed our livestock. Of that, 35 acres are RoundUp Ready Alfalfa ("RRA") and 25 acres are in winter forage.

3. I have signed the Monsanto/Technology Stewardship Agreement and am familiar with the requirements of the Monsanto/Technology Use Guide, including the requirement for harvest at or before 10% bloom. It is my practice to harvest at this time as that is when hay is at its highest feed value.

4. My experience with RRA has been great. My plan was to replace 20 acres of winter forage (which is a rotational crop) with RRA this fall. In my mind, RRA has so many advantages over conventional alfalfa that I would have to be a fool not to plant RRA instead of conventional alfalfa.

5. The benefits of RRA are numerous. First, based on my own tests, the hay you get from RRA is much higher quality with higher total digestible nutrients ("TDN") than conventional alfalfa. Higher TDN means better feed for your livestock. One of the reasons you get higher quality hay with RRA is that you get hay without weeds, which are a real problem with conventional alfalfa. Given that water supplies are tight in our area, we need to be water efficient. One way to be water efficient is to use our water to grow alfalfa rather than the weeds which are prevalent in conventional alfalfa.

6. Gorwing RRA allows me to use RoundUp for weed control as opposed to the herbicides used for weed control with conventional alfalfa. I have a private applicator's certificate from the California Department of Pesticicde Regulation, which I was issued after I

passed a written test, so I have some knowledge about pesticides. RoundUp is not dangerous and does not require me to wear special protective equipment - - the RoundUp label says you should wear a long sleeve shirt, pants and shoes. The alternative chemicals, such as Paraquat, are extremely hazardous - - requiring the applicator to wear full body protection, including a special suit, respirator with special filters, gloves, boots, etc. Since I apply my own chemicals and would like to live as long as possible, I would prefer not to use the extremely toxic chemicals necessary for conventional alfalfa.

7. If the court's order will not allow me to plant more RRA in the fall as I have planned, I probably will not plant additional alfalfa and instead will buy alfalfa from others. RRA is super technology that I need to operate more profitably and efficiently. It allows me to obtain a superior crop at lower cost and lower risks to my health and the environment. Farming is difficult enough and we need more products like RRA that allow us to farm more safely and efficiently.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 20th day of March 2007 at Bakersfield, California.

s/ Joe Marchetti
JOE MARCHETTI

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB DECLARATION OF LELAND TIEGS REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I, Leland Tiegs, declare:

1. I manage an approximately 3,000-acre farm in Nampa, Idaho. I am an alfalfa seed grower and grow Round-Up Ready alfalfa ("RRA") under contract with Forage Genetics Inc., ("FGI"). I previously provided a declaration in this action in support of the Motion To Intervene of John Grover, Daniel Mederos and Mark Watte, a copy of which is attached. I have personal knowledge of the matters set forth herein and if necessary could competently testify thereto.

2. The court's Preliminary Injunction Order places my farming operation at significant risk. I currently have 970 acres, which are devoted to growing RRA seed. I was going to plant another 160 acres of RRA seed this spring, however the court's order has put that on hold.

3. Since de-regulation in the fall of 2005, we have been working towards the goal of putting half of our farm into RRA seed, or 1,500 total acres. Obviously, the court's order puts those plans on hold as well. I currently estimate that I have $300,000 in equipment that is specific to growing RRA seed, including combines, sprayers, bee incubators and other equipment. If I have to stop growing RRA seed the acres currently devoted to that crop cannot be planted with conventional alfalfa seed, assuming contracts were available, for another 3 years. While I could plant those acres with other crops, the profit margin will likely be much less than with RRA seed. Thus, the profit I would expect to make from RRA seed simply cannot be replaced by any other crop. I have geared most of my recent equipment purchases to the production of RRA seed, and if I have to plant other crops I will be undercapitalized as far as the equipment necessary to grow those crops. Thus, I will likely be required to purchase additional equipment.

4. My farm is in a high cost of production area mainly because of the cost of water. Alfalfa seed is a low-water–high-value crop that in large part makes it possible for me to run a profitable farming operation.

5. As a seed grower, I am familiar with the practice of isolation in order assure varietal purity for many different types of seed. Isolation is successful in

maintaining varietal purity in other seed crops that are pollinated by bees. For example, several mile distances are required between fields for different varieties of onion seeds as well as carrot seeds, both of which are pollinated by honey bees.

6. Zero tolerance for contamination is unrealistic in agriculture and to my knowledge has never been the standard for certifying the varietal purity of any seed crop. While some contamination among varieties may occur, the amount of contamination if the required isolation distances are mandated is negligible. If isolation can work in all these other contexts, I see no reason why it cannot work with RRA. In fact, as one who was part of the testing process that led to de-regulation, it is my opinion that practicing isolation will sufficiently protect the growers of organic alfalfa.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 21 day of March 2007 at Nampa, Idaho.

/s/ Leland Tiegs
LELAND TIEGS

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC., and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB DIRECT TESTIMONY OF MARK McCASLIN ON BEHALF OF FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, AND MARK WATTE REGARDING PERMANENT RELIEF DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

I. INTRODUCTION AND QUALIFICATIONS

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. Mark H. McCaslin

Q. WHO IS YOUR EMPLOYER, AND WHAT IS YOUR POSITION?

A. I am the cofounder and current president and research director of Forage Genetics, Inc. ("FGI"), doing business as Forage Genetics, International, a wholly owned subsidiary of Research Seeds, Inc., which is a wholly owned subsidiary of Land O'Lakes, Inc.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I have more than twenty-five years of experience as an alfalfa breeder and have developed more than 300 cultivars during my career. I received my Ph.D. in plant breeding from Cornell in 1981, my M.S. in agronomy from UC Davis in 1976, and my B.S. in plant science and biology from UC Davis in 1974. As president of FGI, I have responsibility for all aspects of FGI's business. I am responsible for FGI's collaborations with key biotechnology partners, including Monsanto Company.

Q. FOR WHOM ARE YOU TESTIFYING?

A. I am testifying on behalf of Forage Genetics, Inc.

Q. WHAT IS THE PURPOSE OF YOUR TESTIMONY IN THIS PROCEEDING?

A. The purpose of my testimony is to provide information to the Court about alfalfa production, FGI's business model, and the Roundup Ready trait stewardship measures that are employed at every step of the breeding, seed production and seed distribution cycle. In addition, I wish to inform the Court of some of the effects a broad injunction would have upon FGI, alfalfa growers, seed companies, and distributors.

II. FGI AND ITS ROLE IN THE DEVELOPMENT OF ROUNDUP READY ALFALFA

Q. WHAT DOES FGI DO?

A. FGI was founded in 1991 as an alfalfa and seed production company serving the U.S. seed industry. Today, FGI is the world's largest alfalfa seed company, with operations in the United States and Argentina, and conventional (non-biotech) cultivar seed sales in more than fifteen countries. FGI develops and produces alfalfa varieties for various market types, including proprietary conventional, organic, and value-added biotech (i.e. Roundup Ready alfalfa and future biotech traits).

Q. WHAT ROLE DID FGI PLAY IN DEVELOPING ROUNDUP READY ALFALFA?

A. Monsanto and FGI co-developed Roundup Ready alfalfa. Monsanto owns the intellectual property around the gene for glyphosate tolerance, and the enabling technology and "know how" to insert genes into plants. Using this intellectual property under a license from Monsanto, and FGI proprietary germplasm, FGI developed Roundup Ready alfalfa cultivars. FGI is the only Monsanto-licensed breeder and seed producer of Roundup Ready alfalfa varieties. FGI has invested more than $8 million developing Roundup Ready alfalfa.

Q. WHAT PERCENTAGE OF FGI'S REVENUES DOES ROUNDUP READY ALFALFA REPRESENT?

A. Since deregulation in June 2005, Roundup Ready alfalfa has been a commercial success for FGI. In 2006, revenues from the sale of Roundup Ready

alfalfa seeds comprised approximately 15% of FGI's total revenues. Demand for Roundup Ready alfalfa has outstripped supply, and demand is rising: to date, owing to the normal multi-year ramp-up process for cultivars seed increase, FGI has been seed supply-limited and therefore the revenue percentage has likewise been limited.

Q. WHAT ARE THE KEY STEPS IN THE PRODUCTION, DISTRIBUTION, AND SALE OF ROUNDUP READY ALFALFA?

A. FGI contracts directly with seed growers who produce Roundup Ready alfalfa seeds. FGI then processes and packages Roundup Ready alfalfa seeds at a small number of company-owned or contracted facilities. FGI sells the seeds, by variety name, to Monsanto-licensed seed companies. The seed companies are authorized to sell Roundup Ready alfalfa seed to Monsanto-licensed forage growers, under the seed company's brands and through the seed company distribution networks. These networks include distributors and/or seed dealers. Throughout each of these steps, FGI and Monsanto impose strict stewardship requirements.

III. STEP ONE: SEED GROWERS

Q. HOW MANY SEED GROWERS DOES FGI WORK WITH?

A. FGI currently has contracts with approximately 400 seed growers, 75 of which produce Roundup Ready alfalfa seed on approximately 19,000 acres in ten western states (Idaho, Washington, California, Nevada, Oregon, Wyoming, Montana, Utah,

Colorado and Texas).[1] The value of the Roundup Ready alfalfa seed to be harvested from current FGI-contracted seed production acres is greater than $15 million in 2007 and a similar amount in 2008.

Q. HOW BIG ARE THE SEED FARMS?

A. Alfalfa seed production is a specialized farming enterprise. Alfalfa seed production is the primary business for most FGI contracted seed growers. To manage seed quality of both Roundup Ready alfalfa and conventional seed production, most FGI-contracted Roundup Ready alfalfa seed growers only grow Roundup Ready alfalfa. The average number of Roundup Ready seed production acres per grower is approximately 250 acres.

Q. WHAT ARE THE KEY TERMS OF FGI'S SEED GROWER CONTRACTS?

A. FGI's Roundup Ready alfalfa seed production contracts typically have three-year terms. This allows growers to amortize establishment costs over three seed harvest seasons. This rotation is typical for all contracted alfalfa seed production in the United States. FGI guarantees the grower a fixed price per pound of seed produced. The average FGI price paid for Roundup Ready alfalfa seed has always been higher than for our conventional seed production. This recognizes the incremental grower cost and effort required to implement the mandatory FGI "Roundup Ready

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[1] In a previous declaration filed in this case, I stated that FGI has contracts for Roundup Ready seed production on approximately 18,000 acres. The number is actually closer to 19,000 acres.

Alfalfa Seed Production Best Practices" ("FGI Best Practices")—a key to our stewardship program for the technology.

Q. WHEN IS ALFALFA SEED PLANTED FOR SEED PRODUCTION?

A. The primary planting season for alfalfa seed production takes place in the fall, with a small percentage planted in the spring. Seed planted in the fall can be harvested the following fall, and annually thereafter for the life of the stand. The seed harvest begins in late August and continues into early fall. There is a rush to get seed harvested before fall rains begin. An untimely rain can heavily damage the seed crop, reducing both seed yield and seed quality. A warm, long, rain-free production season is required for successful seed production, and largely limits commercial production to eight states in the irrigated West. Approximately 95% of U.S. certified alfalfa seed is produced in these states: California, Idaho, Washington, Oregon, Nevada, Montana, Wyoming and Utah.

Q. HOW LONG DOES AN ALFALFA SEED PRODUCTION STAND LAST?

A. An alfalfa seed production contract typically has a three year term. After the end of the contract, the grower is required to destroy the stand to prevent unauthorized seed harvest of the proprietary cultivar. This stand takeout is confirmed by FGI before final payment for seed in the last year of the contract. Approximately 7,000 of the currently planted Roundup Ready alfalfa seed production acres have contracts that will expire this fall; 4,000

acres will expire in the fall of 2008; and the remaining acres have contracts that will expire in the fall of 2009. After removing any alfalfa stand (conventional or Roundup Ready in nature), state crop improvement association requirements for certified alfalfa seed production prevent the field's future eligibility for alfalfa until the field has been without alfalfa for two to four years (requirements vary by state).

Q. WHEN DO SEED GROWERS APPLY HERBICIDES?

A. Seed growers put on a soil-applied herbicide each spring to control weeds and volunteers in alfalfa seed production fields. Unlike Roundup, these herbicides have residual activity, controlling many weeds all season long. Once the residual herbicide is applied, a seed grower cannot take out the alfalfa stand and plant another crop until the herbicide sufficiently dissipates, which may take six to twelve months. I estimate that approximately 60% of the acres currently in production have already been treated with persistent herbicides this year. The remainder of the stands will be treated by the end of April. Roundup Ready alfalfa seed growers will typically also apply Roundup herbicide once each year before flowering to manage weeds not sufficiently controlled by other herbicides (e.g., parasitic dodder).

Q. WHAT TYPES OF STEWARDSHIP MEASURES DO SEED GROWERS EMPLOY?

A. Roundup Ready alfalfa seed growers agree to strict trait stewardship requirements, which are actively enforced by FGI, Monsanto and local crop

improvement associations. These stewardship requirements are designed to, among other things, prevent gene flow from the Roundup Ready seed production field. Gene flow can occur from one seed field to another seed field, from a hay field to a seed field, and from a hay field to another hay field. Gene flow can also theoretically occur from a seed field to a hay field, but this gene transfer is limited by the same biological filters that apply to gene flow from one hay field to another hay field. To ensure that gene flow does not occur from a Roundup Ready alfalfa seed production field, all seed growers must sign Monsanto's Technology/Stewardship Agreement ("MTA") and enter into FGI's Proprietary Seed Services Agreement ("SSA") for the production of Roundup Ready alfalfa seed. The SSA requires, and FGI confirms, that information regarding the planting of Roundup Ready alfalfa seed crops, including the duration, number of acres and location of the fields, is accurate and is reported to the local crop improvement organization. The SSA also requires documentation of the distance and location of the nearest conventional seed field, as well as the contractor for the nearest field. FGI confirms that minimum physical isolation distances are met prior to planting and that the stand has been destroyed at the end of the contract term. The local crop improvement association confirms minimum isolation exists in a field inspection early in the first production year after planting, and subsequently confirms Roundup Ready seed field stand termination.

Q. WHAT ADDITIONAL REQUIREMENTS DOES FGI IMPOSE?

A. The SSA requires seed growers to produce seed in accordance with federal, state, and local regulations, and to adhere to the FGI Best Practices. The FGI Best Practices require seed growers to follow FGI's strict equipment sanitation, pollinator management, and seed handling requirements. Planting equipment sanitation and the purple seed coating applied to all Roundup Ready alfalfa seed prevents admixture of Roundup Ready and conventional seed during planting. Strict limits on pollinator (bee) movement during the season keep Roundup Ready domiciles (bee boards/hives) in Roundup Ready fields for the entire seed production season. Harvest equipment sanitation and placing harvested seed in clearly identified Roundup Ready light aqua-blue colored seed bins prevents admixture during and after harvest. FGI conducts random inspection of all mandated "FGI Best Practices" grower operations. In addition, Monsanto conducts random audits of licensed growers and annual audits of FGI to assess compliance with Monsanto trait license terms.

Q. DO ROUNDUP READY SEED GROWERS RECEIVE ANY TRAINING?

A. All Roundup Ready alfalfa seed producers are required to receive FGI training on mandated best practices to maintain high seed quality and facilitate coexistence with non-Roundup Ready alfalfa seed and hay producers. This one-day course and the written Best Practices were co-designed by FGI and state certifying agencies. The grower training module also includes education on key trait stewardship features contained within the required

Monsanto Technology Agreement (MTA) and Monsanto Technology Use Guide (TUG).

Q. WHAT ISOLATION DISTANCES ARE REQUIRED FOR ROUNDUP READY SEED GROWERS?

A. At planting, all Roundup Ready alfalfa seed production fields must have, at a minimum, a isolation distance to existing non-FGI conventional alfalfa seed fields of 900 feet, one mile, or three miles for leafcutter bees, alkali bees, or honeybee mediated commercial pollination, respectively. These isolation distances are 5 to 85 (depending on the pollinator) times the distances required for certified seed of conventional alfalfa varieties. An FGI study shows that with isolation distances of 1500 feet with leafcutter bees and 1.5 miles with honeybee pollinators, pollen mediated gene flow was less than 0.1%. These FGI Best Practices-mandated isolation requirements were developed by external stakeholder consensus and are based on various publicly available scientific studies on pollen-mediated gene flow in alfalfa.

Q. HOW DID FGI DETERMINE THE ISOLATION DISTANCES?

A. FGI has worked extensively with local state seed certifying agencies and university scientists to ensure that its isolation setback distances are transparent, science-based and appropriate to the pollinator and the region involved. The external participants in the determination are nationally and internationally recognized authorities in seed certification programs or experts in alfalfa breeding or seed production. FGI has broadly communicated

the isolation distance decision-making process, scientific data, trait stewardship objectives, independent third-party oversight, and other Best Practices requirements to the alfalfa seed industry in an ongoing and comprehensive manner.

Q. HOW DOES FGI KEEP TRACK OF WHERE ROUNDUP READY ALFALFA SEED PRODUCTION ACRES ARE PLANTED?

A. FGI and most local state certifying agencies maintain GPS or plat maps identifying the location of all alfalfa seed production acreage. These maps are used to determine a seed grower's initial eligibility to plant Roundup Ready alfalfa in a particular seed production field location and to track field crop history following stand destruction.

Q. HOW DOES FGI ENSURE THAT THE STEWARDSHIP MEASURES ARE FOLLOWED?

A. Roundup Ready alfalfa seed producers are required to allow inspection and audits of their operations at all times by FGI field staff or an official seed certification inspector. Each of our Roundup Ready alfalfa seed growers has been audited at least once in the 21 months since commercial launch.

Q. DOES FGI HAVE ANY ORGANIC ALFALFA SEED PRODUCTION?

A. Through traditional breeding methods FGI has developed alfalfa varieties with resistance to potato leafhopper, the most damaging pest on alfalfa production in the eastern U.S. These varieties have been very popular with organic hay growers. For several years we have tried, without success, to find U.S. seed growers in the eight Western states that

would be willing to produce certified organic alfalfa seed of these varieties. We were disappointed, but not surprised. The Lygus bug is a very serious insect pest on alfalfa seed production in the U.S., and commercial production without chemical control of this insect is exceedingly difficult. I am not aware of any commercial certified organic alfalfa seed production in the United States. We do produce some organic alfalfa seed in Canada, where insect pest pressure is much lower. Because there is no significant supply of certified organic alfalfa seed with excellent multiple pest resistance, winterhardiness, etc., organic alfalfa hay growers are able to purchase and plant non-organic seed of these modern non-biotech varieties. We sell conventionally produced seed of modern non-biotech varieties to several seed company customers that focus on this market.

IV. STEP TWO: PROCESSING AND PACKAGING

Q. WHAT HAPPENS TO THE SEEDS AFTER THEY ARE HARVESTED?

A. After the Roundup Ready alfalfa seed is harvested, it is processed at one of three seed cleaning plants in Nampa, Idaho. More than ninety percent of the Roundup Ready alfalfa seed total is cleaned at an FGI seed cleaning plant dedicated exclusively to Roundup Ready alfalfa seed processing. FGI implements a best management practices standard operating procedure (SOP) to assure that product identity and purity are maintained in its conventional and Roundup Ready seed lot processing. FGI ships the clean seed to one of three

FGI-Roundup Ready trait licensed seed coating companies, which apply the trait-required purple seed coating. At that point, the finished seed product is shipped to licensed seed companies for sale to licensed forage growers.

Q. WHAT TYPES OF STEWARDSHIP MEASURES ARE IN PLACE AT PROCESSING AND PACKAGING FACILITIES?

A. Before packaging into labeled seed bags, all Roundup Ready alfalfa seed is confined to distinctive light aqua-blue colored, covered, steel, bulk seed bins that are clearly labeled as Roundup Ready alfalfa only (capacity 1000 or 2000 lbs). The purple coated seed is packaged in clearly-marked Roundup Ready alfalfa bags also bearing official seed control tags and cultivar (variety) name. Licensed seed company agreements with Monsanto specify the required bag labeling.

V. STEP THREE: SEED COMPANIES

Q. WHAT HAPPENS TO THE SEED AFTER IT IS PROCESSED AND PACKAGED?

A. After the seed is processed and packaged, FGI only sells the seed to Monsanto-licensed seed companies. There are approximately twenty seed companies licensed by Monsanto to sell Roundup Ready alfalfa.

Q. DO MOST SEED COMPANIES SELL ROUNDUP READY ALFALFA?

A. Most of FGI's seed company customers now sell one or more Roundup Ready alfalfa variety as part of their product offerings. For some seed company customers, Roundup Ready alfalfa variety sales constitute almost half of their current alfalfa seed

sales, and the proportion is anticipated to grow over time as seed supplies increase.

Q. WHAT IMPACT WILL RESTRICTIONS ON FUTURE SALES OF ROUNDUP READY ALFALFA HAVE ON SEED COMPANIES?

A. Any restriction on future sales of Roundup Ready alfalfa would have a direct and significant economic impact on seed companies. The retail value of the Roundup Ready alfalfa seed orders for 2007 is approximately $35 million, and the retail value of Roundup Ready alfalfa seed to be harvested in fall 2007 is approximately $60 million. Because it takes normally a year and a half from the time of planting new alfalfa seed production to the sale of seeds, FGI will not have planted enough conventional seed production in 2005 and 2006, harvested in fall 2006 and 2007, to make up for sales lost as the result of a court-ordered moratorium on the sale of Roundup Ready alfalfa seed. Seed companies will face three new problems: 1) cost of storage of existing Roundup Ready alfalfa seed inventory that they purchased from FGI but were prohibited from selling in 2007, 2) lost Roundup Ready alfalfa revenue in 2007 and 2008, and 3) a loss of business associated with a limited supply of their competitive conventional varieties that will not meet total projected alfalfa seed demand in 2007 and 2008.

VI. STEP FOUR: DEALERS AND DISTRIBUTORS

Q. WHO BUYS THE SEED FROM THE SEED COMPANIES?

A. Licensed seed dealers and distributors purchase seed from licensed seed companies for sale to

Monsanto licensed forage growers. Roundup Ready alfalfa seed is currently grown and sold in the U.S. only.

Q. WHO ARE THE SEED DEALERS AND DISTRIBUTORS?

A. Seed dealers are usually independent small business owners with an exclusive license to sell seed of a single seed brand within a specified limited geography (e.g. one or two counties). I estimate that approximately twenty-five percent of the alfalfa seed sold in the United States is sold to growers by seed dealers. Seed distributors generally have several employees that sell multiple agricultural products to farmers (e.g. seed, fertilizer, crop protection). Small local cooperatives, owned by local farmers, are the largest single group of seed distributors in the United States. Land O' Lakes, the owner of FGI, is a regional cooperative owned by local cooperatives and member dairy producers.

Q. WHAT WILL THE IMPACT OF A COURT-ORDERED INJUNCTION BE ON SEED DEALERS AND DISTRIBUTORS?

A. Dealers and distributors may be able to return unsold Roundup Ready alfalfa seed to the Seed company that supplied it. This will vary based on seed company agreements with dealers and/or distributors. However, both dealers and distributors will face two common problems, lost Roundup Ready alfalfa revenue in 2007 and 2008, coupled with a loss of business associated with a limited supply of their competitive conventional

varieties that will not meet total projected alfalfa seed demand in 2007 and 2008.

VII. STEP FIVE: HAY GROWERS

Q. HOW MANY ACRES OF ROUNDUP READY ALFALFA SEED ARE PLANTED FOR HAY?

A. Approximately 200,000 forage acres of Roundup Ready alfalfa are currently under production in the United Sates. Based on current sales, FGI anticipates that up to 350,000 acres of new forage acreage will be planted and placed into production this spring and fall, in the absence of a Court-ordered injunction. FGI anticipates that an additional 538,000 forage acres would be planted in 2008.

Q. WHEN IS HAY PLANTED?

A. In California, Arizona, and New Mexico (the Desert Southwest Region), the planting season starts in the fall and usually concludes in late February. In the Pacific Northwest, the spring planting season started in March and runs until late April. In the Midwest and eastern regions, the spring planting season starts in April and also runs for four to six weeks. There is also a short fall planting season that starts in early August and continues through mid-September in most geographies except the Desert Southwest. Successful fall establishment requires seeding at least six weeks before first frost.

Q. HOW DOES THE CURRENT PRELIMINARY INJUNCTION AFFECT HAY FARMERS WHO USE ROUNDUP READY ALFALFA?

A. Most farmers who plan to plant Roundup Ready alfalfa in either the Pacific Northwest or the

Midwest have made their planting plans and ordered or purchased their seed. The March 30 moratorium imposed by the Court does not leave these farmers with sufficient time to plant their seed and get a return on their investment. Alternative, suitable replacement cultivar conventional variety seed may or may not be available to these growers during the planting window. Growers select their seeds based on variety performance information, brand, price, terms for payment and delivery date, etc. Not all prospective Roundup Ready alfalfa forage growers will be able to replace their seeds with an equivalent conventional replacement in a timely manner. For this reason, a whole season of forage production is at risk. Some purchasers of Roundup Ready alfalfa have already designated their new alfalfa plantings for fields in which, for weed control reasons, conventional alfalfa varieties are not suitable because conventional herbicides are deemed insufficient to successfully establish and maintain the crop, therefore, these growers may opt to forgo alfalfa forage production and a season of crop or forage production may also be lost.

Q. HOW MANY PLANNED ACRES WILL NOT BE PLANTED DUE TO THE PRELIMINARY INJUNCTION THAT IS NOW IN EFFECT? WHAT REGIONS WILL BE MOST AFFECTED?

A. Based on orders from seed companies, and what we believe will be planted by March 30, I estimate that there are approximately 213,000 acres that will not be planted due to the preliminary injunction. Approximately 75% of these unplanted acres are in

states where there is no alfalfa seed production, and no risk of gene transfer.

Q. WHO DO HAY GROWERS SELL THEIR HAY TO?

A. Based on our grower surveys, about 65% of Roundup Ready hay growers feed their hay to their own dairy or beef herds. The remainder produce hay as a cash crop, selling primarily to domestic dairies. About 1.3% of the alfalfa hay produced in the U.S. is sold to export markets. Japan is the largest export market, representing more than 70% of total U.S. hay exports.

Q. HAS ROUNDUP READY ALFALFA BEEN APPROVED IN EXPORT MARKETS?

A. Roundup Ready alfalfa has been approved for hay import in Japan, Mexico, Canada, Philippines, and Taiwan; the regulatory approval in South Korea is pending and is at an advanced stage of the review process. These countries together represent more than 99% of the current U.S. export market for alfalfa hay. In addition, feed approval has been granted in Australia, where little or no hay from the U.S. is imported. Although Roundup Ready alfalfa hay was exported to Japan in 2006 and Japan imports large quantities of other biotech trait feedstuff crops, there are some importers that are asking for non-Roundup Ready alfalfa hay. At the request of the Washington State Hay Growers Association and several hay exporting companies, FGI co-developed a field proven trait testing system, using an inexpensive protein-based test strip that allows hay sellers to easily identify Roundup Ready versus conventional hay (see

Putnam, et. al. 2005). This test system has been widely adopted by hay exporters to allow segregation of hay for particular market channel requirements. This test system mirrors the biotech quality assurance testing systems used successfully for the past decade for the marketing and production of other crops and grains where biotech vs. non-biotech markets exist.

Q. WHAT STEWARDSHIP MEASURES ARE IMPOSED ON HAY GROWERS?

A. There are a number of stewardship measures required from licensed hay growers. For instance, all hay growers must sign the MTA and follow the practices set forth in the Monsanto Technology Use Guide ("TUG"). The TUG sets forth required management practices for Roundup Ready alfalfa hay/forage production. The hay growers agree to produce only forage (i.e., seed production is expressly prohibited in the MTA).

Q. ARE THERE ANY RESTRICTIONS IN THE TUG ABOUT TIMING OF HAY HARVEST?

A. One of FGI's stewardship requirements is that Roundup Ready alfalfa must be harvested at or before ten percent bloom to minimize potential pollen flow from hay to common alfalfa seed production. In addition, the TUG educates Monsanto licensees about principles of market coexistence, instructions for management of pollen flow and mechanical mixing, and generally accepted identity preserved production methods.

Q. DO HAY GROWERS COMPLY WITH THE REQUIREMENT OF HARVESTING AT TEN PERCENT BLOOM?

A. Whether growers produce hay to feed their own animals, or to sell to third party customers, they get paid based on the forage quality of the hay produced. Forage quality (feeding value) begins to drop rapidly after the initiation of flower buds (flowers initiate approximately 25-30 days after the previous forage harvest). Hay harvested after early flower, even five to seven days later, does not generally meet quality requirements for high producing dairy cows, and the hay sells at a sharp discount (approximately 30% less per ton). Hay growers have an economic incentive to harvest before ten percent bloom in order to maximize their economic return.

Q. HOW DOES FGI KEEP TRACK OF WHERE HAY FIELDS ARE LOCATED?

A. Growers who purchase Roundup Ready alfalfa in Western states (AZ, CA, CO, ID, KS, MT, NE NV, NM, ND, OK, OR, SD, TX, UT, WA, WY) must provide field size and GPS locations at the time of purchase to enable monitoring and enforcement of the Monsanto trait stewardship measures.

Q. WHY DO ALFALFA FARMERS CHOOSE TO GROW ROUNDUP READY ALFALFA?

A. Hay growers choose to plant Roundup Ready alfalfa for a variety of reasons. In a November 2006 customer satisfaction survey, hay growers reported that they have better weed control with Roundup Ready alfalfa than with conventional alfalfa, as well as greater yield and higher quality forage for feed. Growers reported that they found ease of use to be an additional benefit. Growers reported that Roundup Ready alfalfa is more profitable than

conventional alfalfa, and they considered it to be a good value because of its superior results. If the Court were to enjoin the planting of Roundup Ready alfalfa, many hay growers would be substantially harmed.

VIII. OTHER ASPECTS OF FGI'S BUSINESS

Q. IN ADDITION TO ROUNDUP READY ALFALFA, WHAT DOES FGI SELL?

A. FGI develops alfalfa varieties and produces alfalfa seed for various markets. FGI's sole business is alfalfa seed and traits. Roundup Ready alfalfa represented approximately 15% of total sales volume in 2006. FGI is the largest developer and producer of conventional alfalfa seed, with significant markets in the U.S. Canada, Mexico, South America, Australia, and the Middle East. Approximately 20% of our conventional alfalfa seed business is outside the U.S., and this is a growing market for the company. Some of these seed export markets either have not yet deregulated Roundup Ready alfalfa for planting purposes (e.g. Australia) or do not have a regulatory system in place for biotech traits (e.g. Saudi Arabia). The seed we produce for these markets is produced in a manner that insures no detectable presence of the Roundup Ready gene, and is tested to validate our claims prior to shipment when required by contract with the seed buyer. FGI sells seed to several seed companies that specifically target organic hay producers. Because there is virtually no certified organic seed of advanced alfalfa varieties that contain the insect and disease resistance characteristics that organic growers demand,

organic certification rules permit the purchase of non-organic seed, as long as the varieties have not been developed with biotech traits. Because of proprietary FGI developed products with outstanding resistance to important insect pests, I believe that FGI is the single largest supplier of seed to organic hay producers in the U.S. For these reasons, FGI has an interest in the viability of the Roundup Ready, conventional, and organic markets, and works to ensure that the three markets can successfully coexist.

Q. DO YOU HAVE ANY FURTHER TESTIMONY?

A. No, that's all.

Thank you.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 23rd day of March 2007 at Prior Lake, Minnesota.

/s/
MARK McCASLIN

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/
B. ANDREW BROWN

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, vs. MIKE JOHANNS, Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE Intervenor-Defendants.	) No. C-06-1075 CRB) DECLARATION) OF ERNEST) JOHNSON) IN SUPPORT OF) PLAINTIFFS) PERMANENT) INJUNCTION)) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor,) Courtroom 8) Judge: Hon. Charles) Breyer

I, Ernest Johnson, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I live at 9265 Paradise Valley Road, Chinook, MT 59523. I am currently President of the Montana Alfalfa Seed Growers Association. This is my third term as President.

3. My father and I started raising Alfalfa seed in 1981 on 20 acres. We expanded our seed acres in 1982, which included contracting with Allied Seed Company.

This transaction provided an additional 30 acres to our farm, and we also hired a custom harvester to combine the crop.

4. In 1984, we purchased a John Deere 95 Combine to harvest our crop. Several years later we obtained another JD95 and have used both of these machines since then and this includes harvesting our 2006 crop.

5. We have always used leafcutter bees to aid in the pollination process of raising alfalfa seed. In 1981 we hired a company to bring bees onto our fields to pollinate our crop. In 1982 we purchased bees from Canada and every year since that time, we have used our own bees to increase the crop. Over the last several years we have increased our acreage of alfalfa seed which has required us to purchase more bees each year. We obtain a positive return on our bees most every year; we get more bees back than we put out on the fields. We purchase new bees from Canada each year, nest these bees in drilled boards. We then sell the wood hives, filled with bee larvae, to two seed producers in the Boise Idaho Valley area.

6. The alfalfa seed industry in Montana is relatively small (about 35 farmers in our state association), but the income from alfalfa seed production accounts for more than 50% of the profit on our farm.

7. Roundup Ready alfalfa became legal for sale in later summer of 2005. Roundup Ready alfalfa has been planted as close as 2 miles from my fields of traditional alfalfa seed production. I understand that under the agreed upon management practices the participating hay farmers agree to not produce alfalfa seed from

these stands or allow the fields to produce significant amounts of blossoms. I am very concerned about the contamination coming in onto my fields because historically the weather of the last week of June, when hay is to be cut, can be very rainy. This prevents the harvest of alfalfa hay - the alfalfa continues to grow and flower and the contamination potential continues to proliferate. When the rains stop and the weather dries, the bees have already spread the pollen to my alfalfa seed fields 2 miles down the road.

8. At the Northwest Seed Growers meeting in January 22-23 of 2007, in Las Vegas, Nevada, we learned of the Bob Hammon study that was commissioned by Forage Genetics to determine how far bees would transfer the Roundup Ready pollen. The results indicated that the pollen was transferred up to 1.7 miles. When I asked Mr. Hammon "how far he would say that a field would have to be away from a roundup ready field and not be potentially contaminated?" Mr. Hammon replied that it would have to be 5 miles away.

9. At the Montana Alfalfa Seed Growers Association meeting on February 15, 2007, Billings, Montana, Mike Huff, a field representative of Dairlyland Seed Col, told us of 16 different lots of traditional Dairyland alfalfa seed that had become contaminated. Mike Huff also informed us of contamination of a Dairyland foundation seed field.

10. At the same Montana Alfalfa Growers Association meeting on February 15, 2007, Rod Leafdale stated that a contamination from a neighboring farmer's field results in a liability issue between the two farmers, and forage Genetics has no

liability in that situation. I am greatly concerned that Forage Genetics is assuming no responsibility for damage to farmers.

11. I produce certified public alfalfa seed varieties, common seed varieties, and proprietary varieties for one of the major seed companies. If the certified public varieties became contaminated with GMO pollen, I cannot receive the "certified" stamp of approval from the Montana certifying agency. Thus this seed becomes non-certified and unmarketable. If my farm becomes contaminated I will lose revenue from 20,000 pounds per year at approximately $1.50/LB for a total of $30,000.00. This economic harm would continue annually because this contamination would persist in my seed stocks.

12. I grow 130 acres of certified non-Roundup Ready alfalfa seed under contract for two major companies, Dairyland Seeds, Inc. and Northstar Seeds. Contamination of this production would result in the loss of $117,000 per year. (130 acres x 750 pounds of seed per acre x $1.20 per pound of seed.)

13. A contamination of my seed fields would also be a deadly blow to my bee sales. Leafcutter bees build their nests out of alfalfa leaf pieces and alfalfa pollen and nectar. The roundup ready gene would become an integral part of the bees. Contaminated bees could not be used on traditional alfalfa without contaminating that field also. Estimated annual loss on bee sales = approximately $28,000 (sale of bees in March of 2007 = $28,000).

14. My total annual loss if my fields were contaminated with Roundup Ready alfalfa would be $175,000.000 ($28,000 + $117,000 + $30,000).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 3, 2007 in Chinook, Montana

_____/s/_____

Ernest Johnson

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF JOHN MARKEGARD IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS, et al.	
Defendants,	
and	) Date: April 27, 2007
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, John Markegard do hereby declare as follows:

1. I have personal knowledge of following and could competently testify if called as a witness.

2. My son and I farm in the Yellowstone Valley near Laurel, Montana. We are currently growing about 800 acres of non roundup ready alfalfa seed under contract for Dairyland Seed, Co., with a contract provision requiring that less then 1% adventitious presence of genetically modified organism ("GMO").

This farm has been an alfalfa seed farm since the early 80's, and we have averaged about 500 acres of seed since the mid 80's.

3. We have been opposed to the roundup alfalfa seed since its introduction in 2004, not on the basis of new technology, but the right to remain free of the roundup gene by contamination.

4. The deregulation in 2005 left us open to cross pollination with the 900 foot isolation requirements set by the seed certification and federal guidelines. According to the published report funded by Forage Genetics, prepared by Bob Hammon, there has been Roundup Ready pollen found as far as 1.7 miles from the source. Our concern is who will be held responsible for the contamination when it does occur.

5. We farm in a small narrow valley which has approximately 1,500 acres of alfalfa seed being raised. The only other two seed producers in the valley have both conventional alfalfa and Roundup Ready alfalfa being raised for seed. The nearest fields with the roundup ready gene are within 1.5 miles from us. As far as I know, no safe isolation requirements have been established.

6. As discussed in the annual Montana Alfalfa Seed Growers meeting held Feb.15, 2007, Rod Leafdale, the local Forage Genetics representative stated that any contamination between GMO and non-GMO growers will be a liability issue between the farmers themselves and not Forage Genetics or Monsanto. I for one prefer not to sue or be sued by my closest neighbor with whom I have lived next to for over 50 years.

7. The risk of contamination in the alfalfa seed business is unique unto itself, because alfalfa is a perennial pollinated by bees. Not only do the leafcutter bees, our main source of pollinators, move the pollen around the area, but wild honey bees visit the fields on a regular basis. Wild bumble bees also come to our fields. Bumble bees are our favorite wild pollinator, because when they show up pollen is guaranteed to get transferred from flower to flower. However, we have no ideas where the wild bumble bees will be the next day because they have a range of five miles or more.

8. Hard seed is another source of contamination. Hard seed is seed that can last in the ground without germination for many years. When germination of the seed is being done to determine the percentage of viable seed, many times the seed will test at 30% hard seed. Seed can be lost from the plant prior to harvest due to hail, rain, or loss out of the combine at harveste. Hard seed can be buried and last in the soil dormant for several years, only to be brought to the surface to sprout years later.

9. When it comes to weed pressure in a seed field, given the sparse population of the alfalfa to raise seed, late season weeds are always a problem in seed fields. We can have some control of these weeds by using a lay-by chemical (such as Prowl H2O, Karmex, Sencor on established fields; Pursuit, Raptor and Buctril on seedling fields) that will give us season long control. It is my understanding, that using just Roundup will not give the producers this added tool for late season weed control. Also, spraying the plant with Roundup at or near bloom will prohibit the maximum potential for seed production.

10. We seldom use roundup alone so we have two modes of action on the target weeds. I do know that Roundup alone will not control Canada thistle or morning glory.

11. If our 800 acres of alfalfa seed were to be contaminated, we could lose the value of of that crop—$800,000.00. If my fields are contaminated, they will remain contaminated for years. I plan to continue alfalfa farming for the next 30 years. Assuming I grow on an average of 500 acres for the next 30 years, at $500,000.00 per year, I could potentially lose $16 Million due to biological contamination from Roundup Ready alfalfa.

I declare under penalty of perjury that the foregoing is true and correct.

I executed this on April 3, 2007 at Laurel, Montana.

/s/
John Markegard

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF DAVID LEE
vs.	) MCSHERRY IN SUPPORT OF
MIKE JOHANNS, et al.	) PLAINTIFFS PERMANENT
Defendants,	) INJUNCTION
and	)
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	)

I, David Lee McSherry, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I submitted a Declaration in Support of Plaintiffs' motion for summary judgment.

3. I reside at 15212 Southwest 79th Avenue, Archer, Florida 32618.

4. My wife and I have been members of the Sierra Club for over thirty years.

5. I own McSherry Farms, and I operate 600 acres and have farmed this land for 32 years. I conduct a cow/calf business where I sell young calves. Additionally, I cultivate alfalfa hay which I market as high-quality livestock-feed.

6. The deregulation of genetically engineered alfalfa threatens to harm my economic interests.

7. I pride my farm-business on being pesticide and genetic-engineering free. I completely avoid Roundup, or glyphosate, due to concerns about its toxicity and environmental impact. I market my alfalfa hay as herbicide-free and pesticide-free which has resulted in my hay being commercially favored among horse breeders who demand the highest quality in their animal-feed.

8. I purchase my alfalfa seed from Cal West Seeds in California where it is grown for Florida. Seed for Florida alfalfa was developed by the Agronomy Department, University of Florida, as a special line of seed selectively bred to be resistant to Florida's phytophthora root rot, anthracnose and the spotted alfalfa aphid. This variety is adapted to the entire state of Florida. Due to various market factors, there are a limited number of alfalfa seed suppliers in Florida.

9. I am concerned that the growing of genetically engineered alfalfa seed will contaminate natural alfalfa seed strains because alfalfa is open pollinated and USDA approved its use, and drift of pollen from genetically engineered plants will adversely affect my own farming practices.

10. This contamination, to which I and other Florida alfalfa farmers are especially susceptible given the limited seed supply, may eventually affect the marketability of my feed. Specifically, consumers could begin to question the integrity of my alfalfa resulting in either increased production cost—for example testing for genetically corruption—or a decreased demand.

11. Furthermore, I feed my cows from my own fields in order to avoid pesticide residues and genetically engineering in commercial animal feed. I raise pure-bred Black Angus calves for market and view maintaining an organic diet for these animals as a commercial advantage. The present deregulation, which creates a risk of contamination in natural alfalfa fields, makes my attempts to avoid these agricultural aspects more difficult, creating a risk of further economic injury.

12. If my alfalfa seed stocks become contaminated, I would likely lose my entire business because currently approximately 100% of my business relies on commercial alfalfa hay production and the sale of Black Angus cattle raised on alfalfa hay. If I lost my business, I would be harmed $60,000 to $70,000 per year in the commercial sale of alfalfa hay and $40,000 to $50,000 annually in the sale of my Black Angus cattle. Total economic damage could be as high as $120,000 annually.

13. If I fed contaminated alfalfa hay to my cattle I could lose the high value of my Black Angus cattle herd that I have bred and selected for thirty years, because the herd would no longer be considered raised and fed genetically engineered free. This economic damage would affect me for many years. I plan to produce

alfalfa hay free of genetically engineered traits for 20 to 30 more years.

14. My sons intend to continue the commercial alfalfa hay business and raise Black Angus cattle free of genetic engineered alfalfa hay on our farm in the future. My sons and I would suffer economic damage that would continue for years because once seed stocks are genetically contaminated, we would not be able to obtain natural, uncontaminated and adapted alfalfa seed. My sons and I would be deprived of a profitable and sustainable business.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007 in Archer, Florida.

/s/
David Lee McSherry

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs, vs.	) DECLARATION OF LARRY MEYER IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
MIKE JOHANNS, et al.	
Defendants,	
and	
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, Larry Meyer, do hereby declare as follows:

1. I have personal knowledge of following and could competently testify if called as a witness.

2. I live at 2074 East 3550N Filer, Idaho 83328. My Farming operation consists of 900 acres. I grow 80 acres of non-genetically engineered conventional alfalfa seed since 1980.

3. I also do custom alfalfa seed combining on 100 to 150 acres per year. Some alfalfa seed farmers do not own there own combine, and they hire me to bring my

combine to their fields to cut their alfalfa seed. I combine Roundup Ready and non-Roundup Ready alfalfa alike.

4. I currently serve on the Idaho Alfalfa and Clover Seed Commission.

5. In September of 2006, Dick Svancara asked to harvest a crop of alfalfa seed for him. He had a field of Roundup Ready Alfalfa and a field of conventional alfalfa seed. I harvested the Roundup variety first. I asked Dick if Gayle, the field man from Forage Genetics, would be there the next day to clean the combine. He told me he would call him that evening. The next morning Dick was cleaning the combine, and he told me that the Forage Genetics field man said to give the combine a quick over and go to the other field. I questioned the cleanliness of my combine, and that Gayle, the Forage Genetics field man, should have been there to do the job. Dick answered that the field man did not have time to clean the combine.

6. Combines are complicated machines, with many moving parts, and lost of places where seed can get lodged and stuck. A simply cleaning with regular tools, and forced air, does not completely clean the combine. Whenever I clean the combine, some seed is always left stuck in the combine. The only way to completely clean the combine is to take much of the machinery apart, a process that is very costly and time consuming.

7. I was surprised that Gayle from Forage Genetics was so casual about me cutting conventional alfalfa immediately after cutting Dick's Roundup Ready alfalfa. Based on many years of combining, there is a very high likelihood that some left over

Roundup Ready seed mixed into Dick's conventional seed when I cut his non-Roundup Ready field. In my opinion Forage Genetics did not do there job to make sure that Dick's conventional alfalfa variety would not be contaminated.

8. On January 14, 2004, I attended an Idaho/Oregon seed grower meeting at the Hampton Inn in Nampa, Idaho. At the meeting, Forage Genetics was ask about how they would deal with combines when it came to contamination. The Forage Genetics representative said that they would make sure that there would be combines dedicated to Roundup only varieties.

9. If my 80 acres of non-genetically engineered alfalfa were to be contaminated with Roundup Ready alfalfa from combine seed mixing or pollen drift, I could lose the entire value of my crop, $125,000 annually. I would also be out of the business to raise conventional alfalfa seed for as long as my fields were contaminated, which is an unknown, but could last for many years.

10. In my opinion, the planting of any Roundup Ready Alfalfa for seed or forage should be stopped until the USDA can determine that there will be no contaminations of any kind.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 4, 2007 in Filer, Idaho

/s/

LARRY MEYER

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C-06-01075 CRB
Plaintiffs,	) DECLARATION OF GEORGE SIEMON IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS,	
Defendants,	
and	
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, George Siemon, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am Chief Executive Officer for the Cooperative Regions of Organic Producer Pools (CROPP Cooperative), an agricultural cooperative located in LaFarge, Wisconsin.

3. CROPP Cooperative's membership is comprised of 941 organic family farms located in 28 states. All members are USDA certified organic farmers, and as such are required to operate their farms in accordance with the Organic Food Production Act of 1990 and the USDA's National Organic Standards.

4. Of the 941 farms, 669 are organic dairy farms and 163 are organic meat or pork producers.

5. CROPP Cooperative markets the products of its members throughout the United States and internationally under the brand name "Organic Valley®." All products sold under the Organic Valley are USDA certified organic. Consumers look to the Organic Valley brand as a signature brand which represents the integrity of the USDA organic seal. This integrity is paramount to the continued success of the organic industry and CROPP Cooperative.

6. Organic Valley is the number one selling organic brand in the Natural Food Retail Channel.

7. In 2006, CROPP Cooperative had a total of $333 million in sales, which represented a 38% growth over 2005 sales. Of this total, $287 million involved sales of organic dairy products, and $7.8 million involved sales of organic meat products. CROPP Cooperative is projecting a 35% growth in 2007, with total sales expected to reach $450 million.

8. In 2006, CROPP Cooperative marketed 580 million pounds of organic milk on behalf of its members. In 2007, CROPP Cooperative has budgeted to sell 830 million pounds of organic milk.

9. Our dairy farmers receive a premium for their organic milk, above conventional prices. In 2006, the average price received by our farmers for a hundred

pounds of milk (cwt) was $24.87, compared to a conventional average price of $13.04 (a difference of $11.83). Our farmers collectively received $68 million in organic premiums in 2006.

10. CROPP Cooperative's dairy membership represents approximately 35% of the total national organic milk supply. CROPP Cooperative's total membership represents approximately 10% of all organic operations in the United States.

The Economic Impact of the Loss of Organic Alfalfa

11. CROPP Cooperative's membership collectively own approximately 42,500 cows. Certified organic livestock may only be fed a diet of 100% certified organic feed. CROPP's members feed their animals a combination of a high forage diet, comprised of approximately 60% certified organic alfalfa, and pasture their animals for the remainder of their diet.

12. CROPP Cooperative's membership grow and produce their own animals' feed, or they purchase 100% certified organic feed from other producers or feed mills.

13. Each cow eats approximately 32.5 pounds of organic alfalfa per day. This equates to approximately 150,000 tons of certified organic alfalfa per year for our members' animals alone.

14. Sourcing adequate organic feed in the United States is a very difficult and expensive issue for CROPP's membership. Organic feed for livestock has been, and continues to be, in very short supply, causing increased prices and supply difficulties for all organic farmers, including CROPP's membership. CROPP has had to initiate a feed program in the past year to assist its members in sourcing adequate certified organic feed at reasonable prices. Many farmers have reported

severe economic impacts, including greatly increased expenses, due to the lack of certified organic feed.

15. If Roundup Ready alfalfa is permitted to be sold commercially, and this causes the contamination of certified organic alfalfa stands, or seed stock, this wll devastate the organic farmers who market their milk through CROPP Cooperative.

16. The purchase of non-certified organic alfalfa is not an option. In order for milk and dairy products to be marketed as organic, certified organic alfalfa must be used as forage.

17. One of the reasons the members of CROPP Cooperative have chosen to be organic producers is because they do not desire to raise genetically-modified ("GMO") crops. They have chosen to raise non-GMO crops, and they will lose this choice if the national crop of alfalfa becomes contaminated with Roundup Ready alfalfa.

18. If certified organic seed is not available, farmers who seek non- GMO seed will be forced to test at great expense, I understand that prices can range from $179 to $259 per sample, depending upon the species and complexity of the test. Farmers will be forced to choose how often they test seed or hay lots and what kind of test to use, simply to ensure that they are planting a crop that does not have GMO contamination, or to ensure that hay that they are purchasing has not been polluted.

19. If the farmers are unable to source adequate organic feed, they will not be able to produce organic milk. CROPP Cooperative does not market conventional milk, and relies on its farmers' consistent production to take the "Organic Valley" brand to market and maintain shelf space. A shortage of feed will affect this production and affect Organic Valley's

ability to compete in the retail channels. If the brand is not able to maintain its presence in the retail channels, the farmers will lose their market, and lose their chosen livelihood of organic farming.

The Consumers' Reliance on Organic representing non-GMO

20. In addition to the production impact of the loss of certified organic feed, the impact of Roundup Ready permeating into the organic food industry could potentially devastate the reliance that consumers have come to hold with respect to the USDA organic seal. For consumers, the seal represents, among other things, a statement that the product if free from genetically modified organisms.

21. Our consumers choose certified organic products for a variety of reasons, chief among them a desire to avoid foods contaminated with GMOs. If consumers come to believe that the USDA organic seal no longer represents a GMO-free product, the integrity of the seal will be greatly compromised. Consumers may no longer choose organic products, and our farmers' market will be greatly reduced.

22. Because the USDA seal does not explicitly promise GMO-free products, several private industry retailers and groups have begun initiatives demanding that manufacturers and processors certify that their products have been grown or processed using no genetically modified materials. Retailers, including Whole Foods Markets, the nation's largest natural food store chain, and distributors, including United Natural Food Inc., are considering private initiatives to demand non-GMO labeling or warranties from processors or producers. Whole Foods is one of CROPP Cooperative's single largest customers, and UNFI distributes CROPP Cooperative's products to natural

food retailers throughout the country, and is CROPP Cooperative's largest customer.

23. If the national alfalfa seed stocks become contaminated with Roundup Ready genes, it will become impossible to feed dairy cattle GMO-free alfalfa, and therefore impossible to market GMO free dairy products. This issue is fast becoming a major issue for organic integrity.

24. Roundup Ready seed production and planting should be stopped, to prevent contamination of the nation's organic alfalfa stocks, until the USDA can ensure that the GMO alfalfa is can be grown in a manner that ensures other alfalfa crops are safe from cross-contamination.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 5, 2007 in LaFarge, Wisconsin.

/s/

George Siemon

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

Supreme Court, U.S.
FILED
MAR 1 - 2010
OFFICE OF THE CLERK

(8)

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
Petitioners,
v.
GEERTSON SEED FARMS, ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

JOINT APPENDIX – VOLUME II
(Pages 651 to 1075)

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PETITION FOR CERTIORARI FILED OCTOBER 22, 2009
CERTIORARI GRANTED JANUARY 15, 2010

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E-mail from Seth Rosmarin to APHIS/USDA re Comments – Monsanto Roundup Ready Alfalfa, Docket #04-085-1, dated Jan. 24, 2005 [AR4067- 69] JA-114

E-mail from David F. Gould to APHIS/USDA regarding Comments Pursuant to Monsanto Co. and Forage Genetics International; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate, dated Jan. 24, 2005 [AR4340- 42] JA-122

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In accordance with Supreme Court Rule 26.1, the following items have been omitted in printing this joint appendix because they appear on the following pages of the Appendix to Petition for Writ of Certiorari filed on Ocotber 22, 2009 by Petitioners in Case No. 09-475.

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THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C-06-01075 CRB
Plaintiffs,	) DECLARATION OF ALBERT STRAUS IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS, et al.	
Defendants,	
and	) Date: April 27, 2007) Time: 11:00 a.m.
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, Albert Straus, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. My name is Albert Straus. I am the President of Straus Family Creamery, Inc. located at 5600

Marshall-Petaluma road, Petaluma, Ca 94952. Our creamery business started in 1994.

3. Straus Family Creamery produces organic, genetically modified organism ("GMO") free dairy products, including milk, butter, yogurt, and ice cream. All of our products are FDA certified organic. Additionally, we are in the process of obtaining GMO-free certification through Genetic ID, the global leader in GMO identification (see http://www.genetic-id.com/).

4. Straus Family Creamery owns 300 head of dairy cattle, and buys milk from two other dairies with 1300 head of cattle devoted to production for Straus Family Creamery.

5. In total, the 1600 head of cattle consume approximately 5,500 tons of organic alfalfa forage per year. Our organic alfalfa is grown by organic farmers in Woodland and Tule Lake, California as well as Winnemucca, Nevada. Straus' dairies spend approximately $1,257,100 per year on FDA certified organic alfalfa forage. Organic alfalfa forage comprises 90% of the cattle forage during July through February when the cattle do not graze in the pasture. During the pasture time, from March through June, alfalfa comprises approximately 50% of the cattle forage, while pasture grass comprises the other 50%. Organic alfalfa forage is irreplaceable for cattle because it provides the highest quality protein, fiber, and energy for dairy cattle. Alfalfa has been the standard forage of the dairy industry for over fifty years.

6. We at Straus Family Creamery are extremely concerned about biological contamination of organic alfalfa from Roundup Ready alfalfa. In an effort to ensure that we can provide the purest organic, GMO free products, we have began testing our alfalfa forage

to ensure that it is GMO free. Currently, we use strip tests costing approximately $20 per test. If Roundup Ready alfalfa is grown commonly, we will be forced to test every organic alfalfa lot coming out of the fields. We use approximately 150 lots per year. Thus, strip testing will cost Straus Family Creamery approximately $3000 per year.

7. Given the importance of maintaining pure GMO free alfalfa for our organic dairy production, Straus Family Creamery plans to upgrade our GMO testing to Polymerase Chain Reaction ("PCR") testing, which is more accurate. This costs approximately $179 per sample, and will cost Straus Family Creamery approximately $26,850 per year when we begin using this new testing method. Given the increasing prevalence of the GMO alfalfa, we are forced to incur this cost to ensure organic purity.

8. We are very concerned about contamination because if our alfalfa forage were to be contaminated with GMO genes, Straus Family Creamery would no longer be able to feed our cattle organic alfalfa and market our dairy products as organic. If our organic alfalfa forage were contaminated with Roundup Ready genes, Straus Family Creamery could not get organic, or non-GMO certification. Because our entire business is based on the organic dairy market, we would lose our entire organic business, causing us $15 Million per year of economic harm.

9. Once our organic and GMO-free alfalfa is contaminated, we will not be able to return to organic production. Thus, contamination from Roundup Ready alfalfa to our organic dairy would cause us harm indefinitely into the foreseeable future.

10. One of our major concerns about Roundup Ready alfalfa production is that there is no requirement that Roundup Ready alfalfa farmers disclose the location of their fields to organic alfalfa farmers. Thus, our alfalfa farmers never know the level of risk they are exposed to. Additionally, if our dairy is contaminated, the legal liability falls squarely on our shoulders. Legal history has shown that there is no legal recourse for us to sue Monsanto, Forage Genetics, or a Roundup Ready alfalfa farmer that contaminated our organic alfalfa forage.

11. Straus Family Creamery plans to begin labeling all of its dairy products as "non-GMO." In order to create this label, Straus Family Creamery needs to be confident that it can procure certified organic, non-GMO alfalfa, and be able to tell consumers the story with honesty and accountability. If widespread contamination of organic alfalfa occurs from Roundup Ready alfalfa production, Straus Family Creamery will not be able to use this new label.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007 in Petaluma, CA.

/s/
Albert Straus

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

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THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al. Plaintiffs, vs. MIKE JOHANNS, et al. Defendants, and MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE Intervenor-Defendants.	) Case No. C06-1075)) CRB)) DECLARATION) OF GARY) ZIMMER IN) SUPPORT OF) PLAINTIFFS) PERMANENT) INJUNCTION)) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor,) Courtroom 8) Judge: Hon. Charles) R. Breyer)))

I, Gary F. Zimmer, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. My name is Gary Zimmer. I am president of Midwestern Bio-Ag, a livestock mineral and organic/biological fertilizer company in the upper Midwest. We have more than 60 consultants, four distribution plants (Wisconsin, Minnesota, Michigan and Iowa), working with over 4000 farms, 60 percent of which are dairy farms.

3. In addition to my duties as President of Midwestern Bio-Ag, I, along with my son Nicholas, own and operate Otter Creek Organic Farm, a 200 cow dairy farm, farming about 1,000 acres. Crops grown are corn, soybeans, peas and forages. We manage about 300 acres of alfalfa forage blends.

4. My education is in dairy nutrition. I hold a Bachelor of Science degree from the University of Wisconsin and a Master's Degree from the University of Hawaii.

5. As a result of my practical experience and research in the field of dairy nutrition and sustainable farming practices, I am often asked to speak to farmers and organizations across the country and the world. One of my specialties is raising livestock, including dairy cows, on a rotational grazing system using pastures with a high digestibility and nutrient-available alfalfa a cornerstone of the system.

6. Our Farm, Otter Creek Organic Farm, produces organic, genetically modified organism ("GMO") free milk. Our farm, and our dairy, is FDA certified organic. Additionally, we recently began making a farm cheese using milk from our pasture grazed herd. Our initial cheese won third place in the U.S. National Cheese Championships in its category. We believe the success of our cheese is based on the high quality forage we feed our herd.

7. In addition to our dairy, Otter Creek Organic Farm raises steers for beef, pigs for pork, and chickens for eggs and poultry. All of our animals are fed on our pastures and from bailage/silage we grow on our farm. This has enabled us to thrive economically even as dairy prices and feed prices fluctuate.

8. Both on my farm and in my consulting business, we take dairy and livestock nutrition from the soil up. Our objective is to feed high levels of highly digestible forages. Alfalfa is a vital component of the program.

9. Commercial use of "Roundup Ready" alfalfa would dramatically affect our farm and business.

10. My company works with an alfalfa breeder to breed and select alfalfa varieties that fit our organic/biological program, are highly productive, and are highly digestible. The seed for these varieties is produced in a major alfalfa growing region in the western United States. If this seed were to become contaminated, not only could we lose the use of these varieties, but this contamination could also affect the desirable traits we select for, such as the plant's digestibility.

11. To my knowledge, Roundup Ready has not been tested for in an animal feeding trial. More importantly than testing, however, is our need to maintain pure, alternative seed sources for working with our farmers in differing field conditions. Not all varieties of alfalfa perform the same in different environments, and having a choice of varieties is a key component of a farmers' planning for a successful farm.

12. My company has invested ten years and well over $1 million dollars in the alfalfa breeding/selection process, running farm trials and marketing our alfalfa varieties.

13. For farmers, the cost of losing these unique varieties would be even greater. Alfalfa based forages are the core of our dairy nutrition programs. Because of the cost of grain and consumer demand, use of grains on organic farms is not a good alternative. We depend

on grazing for production, and this demands high quality forages.

14. At Otter Creek Organic Farm alone, if we could no longer feed our herd with our top quality alfalfa, the cost of losing just 5 lbs/day/cow of milk production, would be over $100,000 a year. That is only on one farm and there are more than 400 organic dairy farms in Wisconsin alone, and does not include the losses incurred on our livestock operation. The loss of unadulterated organic, quality alfalfa would be a huge economic loss to farmers. The direct impact on just the organic dairies in Wisconsin alone would be at least $14,000,000 per year.

15. Besides the organic farmers, the biological farmers would suffer the same potential economic loss from milk on herd health. In addition, conventional farmers choosing no-till farming methods would no longer be able to take out alfalfa with the use of Roundup and then no-till corn into the field, because if only 10% of their alfalfa seed were contaminated with Roundup Ready, they would be forced to use additional herbicides and /or till (plow) the field to eliminate the carry-over. Not only would the cost be greatly increased, it would create an increased potential for soil erosion, especially on our hilly Midwestern dairy farms. This scenario affects most of the dairy farms in the U.S. making this a major management and economic cost. In my experience, two-thirds of conventional dairy farms would be negatively affected by the introduction of "Roundup Ready" and would face higher management costs (extra chemical applications and tractor runs), lower crop yield, and the potential for losing government subsidiesmoney for conservation practices when dealing with contaminated alfalfa fields.

A conservative average of the cost to conventional dairy farms would be $10,000 per farm, which does not include the potential for lower milk yield. I believe there are over 30,000 individual dairies in the Midwest region, which would translate to $200,000,000 in lost revenue each year for those farmers.

16. In summary, the use of "Roundup Ready" alfalfa, and its inevitable contamination of other alfalfa varieties, will have a large economic and management cost affecting thousands of dairy farms in the Upper Midwest alone.

17. Beyond the direct impact of contamination, in my professional opinion the negatives of "Roundup Ready" far outweigh any possible positives. There are extra chemical and/or tillage costs associated with its use. This is especially true when corn follows alfalfa in the rotation, and there is a need to completely kill out the stand so the alfalfa won't compete with the corn and lower yields. Additional tillage to kill out a stand presents erosion problems. In addition, digestibility and possible feed effects on cow health has not been studied, and this area could be a major additional economic burden.

18. For organic farmers, Roundup Ready is an even greater concern. Contamination of the carefully developed, highly digestible alfalfa varieties essential to organic production would force organic farmers either to use inferior alfalfa varieties, or abandon alfalfa entirely. Either choice is an economic disaster for individual farmers who stand to lose thousands of dollars in income, and a blow to the organic market which is growing rapidly due to consumer demand.

19. Beyond the economic impact on farmers, there would be a large economic impact on the agribusiness

companies who serve them, such as Midwestern Bio-Ag, who have invested years and millions into developing alfalfa varieties for organic and other farmers who would lose this irreplaceable tool. The companies would also face the specter of lawsuits of farmers who lost their organic certification due to contaminated alfalfa.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 5, 2007 in Middleton, Wisconsin.

/s/
Gary F. Zimmer

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF MIKE NICHOLS IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS, et al.	
Defendants,	) Date: April 27, 2007
and	) Time: 11:00 a.m.
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, Mike Nichols, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I live at 29508 Hurtz Road, Parma, Idaho, 83660. I've been a farmer since 1982. My farming operation consists of 1,000 acres. I grow between 300-400 acres of non-genetically engineered conventional Alfalfa seed every year. I've been growing alfalfa seed since 1983.

3. I'm currently serving my second term on the Board of Directors for the Idaho Alfalfa and Clover Seed Commission. My first term on this commission, I served as chairman from 1997-2001. I am also past president of the Board for the Idaho Alfalfa and Clover Seed Growers Association. Additionally, I am the chair of the Board of the Idaho Seed Indemnity Fund.

4. I currently have a contract to grow non-genetically engineered conventional alfalfa seed with Pioneer Hi-Bred.

5. The potential contamination of my alfalfa seed crop with the Roundup Ready trait is highly probable because alfalfa is a perennial crop which is pollinated by bees.

6. On November 2, 2006, I attended an Idaho Crop Improvement Association meeting in Meridian, Idaho at 55 S.W., 5th Ave., Ste. 150. During this meeting, Gregory Lowry, Executive Vice President of Idaho Crop Improvement Association gave an update in which he described that Dairyland Seed based in Homedale, Idaho had detected contamination in nine Montana fields, one Wyoming field and one Idaho field.

7. On November 2, 2006 at the same previously described meeting, a Dairyland Seed Representative, Doug Gross, confirmed that the eleven lots of non-genetically engineered alfalfa tested positive from a trace to a .9 percent Roundup Ready contamination at distances up to 1.5 miles.

8. On January 16, 2007 at the Hampton Inn and Suites in Nampa Idaho, I attended the Idaho Alfalfa and Clover Seed Growers Association Annual Meeting. Again, during a round table discussion, I heard Doug Gross, a Representative for Dairyland Seeds state that they had confirmed that sixteen lots of non-genetically

engineered alfalfa seed had tested positive for Roundup Ready contamination.

9. Based on the knowledge I've gained, I have concerns about my own operation and the future of the Idaho alfalfa seed industry. In my opinion, the pollen flow studies which are based on nine hundred feet, are flawed and obviously didn't include all pollinators of alfalfa seed. The proposed isolation distances of 1500 feet, 1 mile and 3 miles are inadequate because pollen flow studies do not confirm what I understand to be happening in the real world of alfalfa seed farming. We simply do not know yet how to prevent contamination. I think that Roundup Ready seed should be not be sold or planted until the USDA determines how to prevent contamination from continuing. For the integrity of the Idaho Alfalfa Seed Industry, and our reputation as a premier conventional alfalfa seed growing area, we have to have more information so conventional alfalfa seed can always be grown in Idaho free of contamination from Roundup ready traits. Alfalfa seed is the second largest seed crop in the state of Idaho, with a cash value to growers of over sixteen million dollars annually, according to the Idaho Seed Indemnity Fund.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007 in Parma, Idaho.

_____/s/_____
Mike Nichols

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF TOM BAXTER IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	)
MIKE JOHANNS, et al.	)
Defendants,	)
and	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor,) Courtroom 8) Judge: Hon. Charles) Breyer
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	)
Intervenor-Defendants.	)

I, Tom Baxter, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. My name is Tom Baxter. I live in Canyon County, in Southern Idaho. I live at 13577 Walker Lake Road, Caldwell, ID 83607.

3. I have been a 400 acre alfalfa seed grower for thirty years. I own non-genetically engineered conventional alfalfa genetics and proprietary varieties

through an ownership interest in an independent seed company which markets alfalfa seed and grass seed nationally. My 400 acres of seed production produces approximately 400 thousand pounds of non Roundup Ready seed per year, about 25% of our company's annual production, worth approximately $850,000. Our company markets seeds to customers who do not want Roundup Ready traits in their alfalfa seed.

4. Our business invests significant resources into researching and developing conventional alfalfa varieties free of genetically engineered traits. Currently, our company has developed, and owns the genetics of 10 marketable varieties. We also have in the research and development pipeline approximately 50 to 60 new varieties which could be marketable within 2 to 3 years. Our company invests approximately $25,000 in developing each new variety.

5. On January 16, 2006, I attended the Idaho/Oregon Alfalfa Growers Association meeting in Nampa, Idaho. At that meeting, I learned that some seed companies had contamination issues in the 2006 growing season. I heard Dairyland Seed Company's representative, Doug Gross, report contamination events their company had in 2006.

6. After learning about these contamination events, and based on my years of alfalfa farming and alfalfa breeding, it is my opinion that this contamination issue is going to threaten all non-Roundup Ready conventional alfalfa genetics if not controlled. While I have not been contaminated yet, I believe it is only a matter of time.

7. It is my belief that further *independent* studies are needed to ensure that Roundup Ready and non-

Roundup Ready technologies can be safely produced without threatening each other.

8. If biological contamination occurs in our company's seed stocks, we could be economically harmed $2.5 Million annually in lost non-Roundup Ready seed sales. Additionally, contamination threatens the purity of our proprietary seeds lines. To date, our 10 marketable seed lines have approximately $250,000 of research and development invested into them. Additionally, within 2 to 3 years, our approximately 50 to 60 new varieties will have approximately $1.25 Million to $1.5 Million of research and development invested in them. If these seed lines are contaminated, we could be economically harmed by $1.25 Million to $1.5 Million.

9. Our company believes that seed supplies will be adequate to meet market demand for the 2007-2008 planting season.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007 in Caldwell, Idaho.

/s/
Tom Baxter

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs, vs.	) DECLARATION OF KEVIN GOLDEN IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
MIKE JOHANNS, et al.	
Defendants,	
and	)
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	)

I, Kevin Golden, do hereby declare as follows:

1. I am an attorney admitted to practice law in California. I am a staff attorney with Plaintiff Center for Food Safety and counsel for Plaintiffs in this action. I make this declaration based upon my own personal knowledge and if called upon to testify, could and would do so competently.

2. Attached as Exhibit A is true and correct copy the Center for Food Safety's August 3, 2005 Sixty Day Notice of Intent to Sue submitted to APHIS.

3. Attached as Exhibit B is true and correct copy of the November 18, 2005 Second Sixty Day Notice of Intent to Sue of the Center for Food Safety, Beyond Pesticides, and Sierra Club submitted to APHIS.

4. Attached as Exhibit C is a true and correct copy of a letter written by Paul Frey, President and Chief Executive Officer of CalWest Seeds, which was addressed and faxed to Mr. Thomas Sim IV, the Director of the Animal and Plant Health Inspection Service's Biotechnology Regulatory Service, on April 5, 2007. This faxed letter was copied to Monsanto, Forage Genetics, and the Center for Food Safety. The San Francisco office of the Center for Food Safety received the faxed letter on April 5, 2007.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 6, 2007 in San Francisco, CA.

_____

Kevin Golden

[Logo omitted]

P.O. BOX 1428 • WOODLAND,
CA 95776 (5330) 666-3331

CAL/WEST Seeds

www.calwestseeds.com

April 5, 2007 - Via Fax
Mr. Thomas Sim IV - Director
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
USDA
4700 River Road, Unit 147
Riverdale, Maryland
20737

Dear Sir,

This letter is intended to provide the USDA with information relating to the current review of the legal and regulatory affairs associated with Roundup Ready alfalfa. Our objective is to participate in developing a solution whereby GMO alfalfa can coexist with conventional alfalfa.

Cal/West Seeds is a farmer (seed grower) owned cooperative specialized in breeding, producing, conditioning and marketing seeds Alfalfa is a very important part of our business. We supply hundreds of seed companies in over 30 countries with seed of proprietary varieties. Our company has been in business for over 70 years and was one of the first companies to invest in alfalfa varietal development during the 1950's.

We believe biotechnology is a valuable tool that is bringing significant improvements to agriculture. Cal/West Seeds was one of the first US alfalfa breeders

to initiate bio-tech research over a decade ago and we are actively working on a number of bio-tech projects in alfalfa. Our subsidiary, Producer's Choice is licensed by Monsanto and Forage Genetics to sell Roundup Ready alfalfa.

We are very active in International alfalfa seed markets and we believe that traditional markets, such as these, should not be unduly disrupted by the introduction of biotechnology. This requires developing methods, procedures and enforcement that enable co-existence. Significant precautions are justified, given the fact that alfalfa is a perennial species that flowers over an extended period and requires pollination by bees. This is further complicated by the fact that there are a relatively small number of alfalfa seed growers that are often times concentrated in comparatively small geographic areas. These factors unique to alfalfa substantially increasing seed contamination potential.

Each year the United States exports alfalfa seed valued in excess of $40,000,000.00. The majority of the countries that import US grown alfalfa seed either have a zero tolerance policy or do not have a regulatory framework in place to deal with GMO alfalfa. The US exports of alfalfa seed represent an important market that is not governed by US federal and/or state agencies. This fact needs to be given strong consideration by all concerned. At this point in time, it is clearly in the best interests of the US industry to maintain the ability to produce GMO free alfalfa seed. Recent court decisions and initiatives by grower groups seeking GMO free zones underscore concerns related to this issue.

Federal agencies deregulated Roundup Ready Alfalfa in July of 2005. While the trait was regulated, Forage Genetics and Monsanto were required to follow rigorous USDA-APHIS guidelines designed to prevent unintended gene flow to non-GMO alfalfa seed. In spite of these significant and diligent efforts, we detected the presence of the EPSPS Roundup Ready gene in both our foundation seed and certified seed prior to deregulation.

We first discovered the unintended presence of the Roundup Ready gene in our conventional alfalfa seed in 2005. It was identified in one of our foundation seed production lots grown in California. We tested the foundation seed lot prior to shipping it to a producer who intended to plant it for organic seed production. A representative sample of the seed lot was sent to a qualified lab and tested positive for the CP4EPSPS gene at the .01% level. The sample was tested again and was found positive at the .03%. After discovering that the foundation seed had been contaminated, we initiated tests on certified seed grown at three different field locations in Washington State using the same foundation seed lot. Seed from two of the three locations tested positive at the .01% level. The foundation seed was produced in 2003 in a field located in Solano County California. We didn't discover that it contained the Roundup Ready gene until after it had been used to plant the certified fields. Cal/West Seed had zero access to Roundup Ready seed at that time; therefore we assume the contamination originated from an external source.

It would appear that there was a significant amount of Roundup Ready alfalfa seed production in place in 2005 prior to deregulation. Given the nature of this crop,

this is concerning to us. We had a situation near Powell, Wyoming in the spring of 2005 that provides an illustration for our concern. We contracted with a grower who planted a proprietary alfalfa seed production field on behalf of Cal/West Seeds. We were unaware that there was a Roundup Ready alfalfa seed field planted the same spring by a neighbor less than 200 feet away. A few months later Roundup Ready was deregulated. We harvested seed from the Cal/West Seeds field and sent samples for testing. Lab results showed between .5% and 1.5% of the seed tested positive for the CP4EPSPS gene. After the first year Forage Genetics asked the grower to remove the Round-up Ready production and the grower complied.

These findings underscore the relative ease with which gene flow occurs in alfalfa and the inherent risks that exist for traditional markets. Deregulation without geographic restriction and/or mandatory isolation creates imminent risk for some market segments.

We are concerned that current protocols did not adequately prevent unintended gene flow. Thankfully, neither of these situations resulted in damage to Cal/West Seeds due in part to the fact that we could market the seed containing adventitious presence in the US once deregulation occurred. Under dissimilar circumstances the outcome could have been quite different. For example if deregulation had not occurred or if our production had been for either an organic or GMO sensitive market we could have suffered economic loss.

Cal/West Seeds has identified critical steps in the development, production, conditioning, and shipment of

alfalfa seed and developed a working plan that specifies, in some level of detail, actions that can be taken to ensure our ability to produce, condition, and ship GMO-free seed. It is reasonable to assume other companies have taken similar actions. However, in the absence of both strong collaboration and cooperation between the industry stakeholders or the establishment of mandatory regulations enforceable by a recognized authority, the alfalfa industry will continue to struggle with the co-existence of biotech and conventional alfalfa.

As previously stated we support biotechnology in alfalfa combined with the ability to co-exist with the traditional business. Due to the unique nature of alfalfa we feel that the USDA should provide leadership in developing a means to this end. In order to do so, we believe it is imperative for the USDA to seek and give serious consideration to the facts from all industry stakeholders.

Based on our experience in alfalfa seed production and the facts presented in this letter we are of the opinion that the minimum isolation standards between GMO and non-GMO alfalfa seed production suggested in the recent USDA declaration filed in court case # C 06-01075 are inadequate depending on the level of the GMO trait frequency, if any, that may be acceptable for non-GMO markets Assuming the USDA has an interest in developing systems that foster co-existence, perhaps it would be useful to think in terms of what the isolation standards would need to be in order to ensure that the GMO product could not be contaminated by pollen from another alfalfa seed field if for some reason, which may or may not be science based, the

marketability of the GMO product was impacted from unintended pollen transmission.

If Cal/West Seeds can provide any assistance feel free to contact me.

Sincerely,

/s/ Paul Frey
Paul Frey
President/CEO

Cc: Monsanto, Forage Genetics, Center for Food Safety

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF DOUG GURIAN-SHERMAN IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS, et al.	
Defendants,	
and	) Date: April 27, 2007) Time: 11:00 a.m.
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	)

I, Doug Gurian-Sherman, do hereby declare as follows:

20. I have personal knowledge of the following and could competently testify if called as a witness.

21. I am the Senior Scientist for the Food and Environment Program of the Union of Concerned Scientists ("UCS"). UCS is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective

citizen advocacy to achieve practical environmental solutions. Prior to my position with UCS, I was Senior Scientist at the Center for Food Safety in Washington, DC from 2004 to 2006. Previously, I was founding co-director and science director for the biotechnology project at the Center for Science in the Public Interest (CSPI). I went to CSPI from the U.S. Environmental Protection Agency (EPA) where I was responsible for assessing human health and environmental risks from transgenic plants and microorganisms and developing biotechnology policy. Before joining the EPA, I worked in the Biotechnology Group at the U.S. Patent and Trademark Office.

22. I obtained my B.S. degree from the University of Michigan School of Natural Resources and master's and doctorate degrees in plant pathology from the University of California at Berkeley. After obtaining my doctorate, I conducted post-doctoral research on rice and wheat molecular biology with the U.S. Department of Agriculture. I am the author of numerous papers and reports on agricultural biotechnology and I have frequently advised and testified before government agencies regulating genetically engineered crops.

23. A true and correct copy of my Curriculum Vitae is attached to this declaration as Exhibit A.

24. As the Senior Staff Scientist for the Center for Food Safety, I helped to prepare public comments on the proposed APHIS deregulation of Roundup Ready alfalfa.

25. This declaration concerns the development of weed resistance to the herbicide glyphosate, called Roundup, and the threat of biological contamination of

organic and conventional alfalfa with genetically engineered Roundup Ready ("RR") genes.

WEED RESISTANCE

26. I am qualified as an expert to consider the issue of weed resistance because of my doctorate in plant pathology, where resistance issues concerning plant pathogens are often addressed. In addition, I have written on the subject of glyphosate resistant weeds, and my department at US EPA was responsible for regulating resistance issues for GE insect-resistant crops.

27. I have reviewed the Administrative Record in this case. Since the Court issued its Summary Judgment Order, to my knowledge, the USDA, Monsanto or Forage Genetics have not proposed any new measures that would reduce the increase of weed resistance to the herbicide Roundup. The only new element that is argued by the defendants to affect weed resistance is that the period during which resistance may occur, the preparation of the EIS, is reduced compared to growing the crop indefinitely after deregulation. This is a change in circumstance rather than a measure imposed with the intention to prevent resistance, and I address it in my comments below. The regulatory measures proposed by the USDA and supported by Monsanto and Forage Genetics do not address the problems associated with increased Roundup resistance.

28. I have read the sections addressing weed resistance in the declarations of Dr. Undersander and Dr. Putnam, and the entire second declaration of Dr. Pierson, and exhibit D (Technology Use Guide) from Dr. Pierson's first declaration. Under the proposed APHIS and Monsanto provisions for allowing farmers

to grow RR alfalfa during the preparation of the EIS, there is likely to be a considerable increase in the conditions that have led to glyphosate resistant weeds, and this could exacerbate the resistant weed problem. Once resistance develops, it is often very difficult or impossible to eliminate.

29. I will devote the next several paragraphs of this declaration explaining why RR alfalfa may increase the development and spread of glyphosate resistant weeds, and why this is important. I will spend the rest of the section of my declaration on weed resistance considering the relevant points in the three declarations of the defendants, and the technical use guide provided by Monsanto that is intended to mitigate the resistance problem.

30. The advent of RR crops substantially increases the likelihood that glyphosate-resistant weeds will develop. Although the general mechanisms of resistance are the same as resistance to other herbicides—the selective survival of rare resistance genes that naturally occur in the weed population, by reducing competition by non-resistant weeds—the nature and extent of RR crops increases the development of resistant weeds substantially. For example, some crops are naturally resistant to some herbicides, for instance corn is resistant to 2,4-D or similar herbicides. But it is unprecedented that several of our most widely planted crops, such as corn, soybeans, and cotton, are all resistant to one herbicide, and where that herbicide is so widely used. RR alfalfa, as a major acreage crop, would contribute substantially to this trend.

31. Glyphosate herbicides are now the most widely used in the world, due to RR crops, and this

tremendous selection pressure very strongly favors resistant weeds. This has substantially increased both the number of glyphosate resistant weeds, and their geographic extent (see: http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12 (Note that "glycine herbicides" is another term for the class of herbicides that include glyphosate, and for which glyphosate herbicides are currently the only example) (R Roberson, "Pigweed resistance a nightmare for Carolina grower," Sept. 27, 2006, Southeast Delta Farm Press; D Bennett, "Glyphosate-resistant pigweed nightmare for cotton producers," Dec. 1, 2006, Delta Farm Press; L James, "Resistant weeds concern for farmers," March 31, 2006, Delta Farm Press; JL Jenkins, "Proactive management to protect against glyphosate-resistant weeds," Jan. 3, 2007, Delta Farm Press, a true and correct copy is attached hereto as Exhibit B). The vast acreage under RR crop cultivation also encourages the more rapid spread of resistant varieties of weeds, because they are selected, or favored, in an extensive geographic area.

32. The more types of RR crops that are grown, the more selection pressure toward resistance. This is especially true because one RR crop may follow, or be rotated, with another. It is widely recognized that one of the most important ways to slow the development of resistance is to sequentially use different herbicides from year to year (or within a single year). This commonly occurs when different crops follow one another, are rotated, in a field over time, because different herbicides may be better suited to different crops. However, when two or more RR crops are rotated, weeds that infest them will often be treated only with glyphosate. Common crop rotations include

corn and soybean, or corn and alfalfa. Both corn and soybeans have widely grown RR varieties, so adding RR alfalfa will add to the rotation selection for resistant weeds. Furthermore, because (unlike most other herbicides), glyphosate kills a very large number of weed species, growers are less likely to use other herbicides with glyphosate. For these reasons, adding additional RR crops, especially ones like alfalfa that are grown on 22 million acres nationwide, cumulatively adds to the likelihood of resistant weeds.

33. In addition to selecting for new resistant weeds, RR alfalfa may exacerbate the spread of weeds that have already developed glyphosate resistance. For example, horseweed, pigweeds, and ragweed that already are resistant could be further selected and spread if they find their way into RR alfalfa fields. Because these resistant weeds are already causing problems, exacerbating these problems should be a serious concern.

34. Furthermore, glyphosate is a highly desirable herbicide for many farmers because of its broad spectrum of activity (the many weeds it can kill), and because it has no residual activity (breaks down quickly), and therefore crops can be grown in treated fields soon after it is applied. Many other herbicides have residual activity, restricting when and which crops may be grown after its use. For these reasons, glyphosate resistant weeds are especially problematic, because they reduce the effectiveness of a particularly important herbicide. This is even more so, since new broad-spectrum replacements are not in development, as far as can be determined.

35. RR alfalfa adds additional concerns for weed resistance. It is grown widely in regions that do not

currently grow much of the current RR crops, as well as regions where other RR crops are widely cultivated. Growing in new areas, especially in the West, adds new risks for resistance. This risk extends not only to current RR crops, but also to non-RR crops where glyphosate is important. For example, in the West, alfalfa may be rotated with wheat, and some of the weeds that are important in alfalfa, such as downy brome, are also important in wheat. Although currently no RR wheat is cultivated commercially, glyphosate is important for "burndown" of non-RR wheat, and for chemical fallow, where the land is left fallow to recharge with moisture, and weeds are controlled with herbicides. Glyphosate is often the herbicide of choice for these purposes. In addition, RR wheat has been approved, and could therefore legally be cultivated at any time. It is therefore also important to consider that glyphosate-resistant weeds that arise in RR alfalfa may impact farmers growing different crops. This has not been considered by any of the defendant declarants.

36. Another important question is whether a period of two years, the time allegedly required for EIS preparation, could be sufficient to contribute to resistance. The answer is yes. Resistance is a continuous process that occurs over time. Two years is enough time to substantially enhance the percentage, or frequency, of plants of a weed species that harbor resistance genes. This would increase the possibility that economically important levels of resistance could emerge in another RR crop more quickly, even if APHIS decided not to allow RR alfalfa (or required substantial restrictions on its cultivation). For example, in 2002, a Scientific Advisory Panel

recommended, and EPA agreed, that a mandatory resistance management plan would be enacted over the 3 years of a conditional approval of Monsanto's Bt MON863 corn due to resistance concerns. Monsanto's Technology Use Guide (TUG) and APHIS provide no mandatory resistance management that could provide similarly effective resistance prevention (in particular, requirements to alternate or tank-mix Roundup with other herbicides) ("Transmittal Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held August 27-29, 2002," a true and correct copy is attached hereto as Exhibit C, see Part B). It is difficult to estimate how likely this would be, but it is a distinct possibility.

37. It is also not possible to accurately predict how long an EIS may require to complete. For example, issues may arise in the course of preparing the EIS that require additional experimentation. Such experimentation might involve determining the frequency of resistance genes present in various alfalfa weeds, or better determining rates of gene flow by cross pollination. Such experiments, or others, are time consuming because they are carried out in the field, and could add several years to an EIS. Additionally, it is possible that an EIS will ultimately determine that deregulation is not feasible.

38. For all of the foregoing reasons, development of glyphosate resistant weeds in RR alfalfa is a serious concern, even for a period of only a few years.

39. Dr. Pierson begins her consideration of weed resistance at para. 35, by pointing out that herbicide resistant weeds are nothing new, and that there are many weeds resistant to many herbicides in the US. She then goes on to say that weeds are less likely to

develop resistance to glyphosate than to other herbicides. Whether resistance develops to other herbicides is irrelevant to the harm caused by glyphosate resistance weeds. In any case, however, Dr. Pierson omits an important part of the resistance equation, which is the amount of an herbicide used. Since the introduction of RR crops, the use of glyphosate herbicides has increased dramatically, so that now they are the most widely used herbicides in the world. As is well known in biology, especially population genetics, the higher the levels of selection for resistance, in this case by heavy use of glyphosate, the more likely that resistant weeds will develop.

40. The tremendous use of the herbicide Roundup makes it susceptible to creating resistant weeds. Importantly, that use is directly attributable to the development of RR crops, since the use of glyphosate herbicides was only a fraction of current levels prior to these crops. Therefore, the issue of the development of several glyphosate resistant weeds is directly and causally connected to the development of RR crops.

41. In addition, because glyphosate is a broad-spectrum (kills many species of weeds), or non-selective, herbicide, it is typically used without other herbicides. Other herbicides are often combined because they cannot control all of the types of weeds that may infest a crop. As is also widely accepted, alternating or combining the use of several different types of herbicides reduces the likelihood that resistance will develop, because a weed must develop several types of resistance at once. Therefore, both the nature of RR crops and the herbicide itself facilitate the development of RR resistant weeds, unless

adequate measures are taken to prevent this from occurring.

42. Dr. Pierson's discussion of the way glyphosate works, i.e., attacking a specific enzyme in the plant, is in general irrelevant to the discussion. In fact, other herbicides that are very susceptible to resistance development, such as ALS inhibitors or ACC inhibitors, also attack specific enzymes (different enzymes than glyphosate). Resistance does not have to arise due to alterations of the target enzyme (as does occur to ALS inhibitors), but can occur by other means such as resistance to uptake or movement of the herbicide through the plant, or inactivation of the herbicide. In any case, it is clear from the development of several glyphosate-resistant weeds that such resistance is quite feasible.

43. Dr. Pierson, at 37-40, discusses Monsanto's weed resistance management plan. However, the general principals of resistance management have been widely known and disseminated by agricultural scientists for years, but with little apparent success. This is probably because this advice is often not adopted by farmers. In particular, one of the most widely agreed upon and important methods to limit resistance is the use of different types of herbicides. However, as noted above, there are several reasons that this is often not done with Roundup.

44. For example, Monsanto's Technology Use Guide (TUG) (Pierson at 40, and Pierson first declaration, exhibit D), only requires growers to "(v) tank-mix other herbicides with Roundup *if necessary for the control of weeds* after the crop has emerged." (emphasis added). This practice is inadequate for several reasons. First and most importantly, it is

optional, at the discretion of the farmer. Second, it does not differ significantly from typical advice provided by weed control extension scientists and crop advisors over the years, during which glyphosate resistant weeds have emerged. Second, many herbicides cannot be easily used on the crop after it has emerged (which is one of the reasons that herbicide-resistant crops are desired). Third, it is not a trivial decision to treat uncontrolled weeds, because they may not be plentiful (i.e., not economically significant, and costly to treat), and because they are more often due to "escape" rather than resistance. Escape typically occurs when a weed is missed by the sprayer, and if this is suspected, the farmer may simply reapply glyphosate on a spot basis (which will not kill a resistant weed). In fact, the TUG recommends in the last bullet of the "Weed Resistance Management Guidelines," (WRMG) that growers "Report *repeated* non-performance to Monsanto or your local retailer." (emphasis added). By the time repeated failures of weed control occur, there is a good chance that a resistant weed would already have spread.

45. As part of the TUG, Monsanto recommends starting with a "clean field," but the last page of the TUG recommends using Roundup for pre-plant burndown (this term connotes the use of an herbicide to prepare a field by removing virtually all of the weeds) . If anything, combined with later applications of Roundup, this will exacerbate weed resistance by providing greater selection for resistant weeds. Proper weed resistance management would ensure that a different type of herbicide was used for burndown.

46. Finally, by definition, resistant weeds are initially a very rare event. Therefore, until the resistant weed reproduces, it is likely to be a lone plant, or one of few plants, in the field. This can easily be overlooked by a farmer, especially one growing many acres of a crop. By the time resistance is suspected or determined, the resistant weed has often spread and cannot be readily contained.

47. In addition, Monsanto's steps (iii) and (iv) of the TUG can often be thwarted by adverse, but common events, such as substantial rain preventing timely herbicide application. In fact, one of the selling points of RR crops is the flexibility of application timing it provides to farmers. The very nature of RR crops encourages poor timing in some instances.

48. The result has been increasing numbers of glyphosate resistant weeds (see: http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12). For example, the development of the first and most widespread glyphosate resistant weed, horseweed, occurred due to use of glyphosate alone for several years (Van Gessel, Weed Science, Glyphosate-resistant Horseweed from Delaware, 49: 703-705, 2001; a true and correct copy is attached as Exhibit D). This is also believed to be the case for at least several other glyphosate resistant weeds that have developed due to RR crops. Therefore, it is clear that the resistance management plan that Monsanto proposes adds little to previous practices, and is likely to do little to mitigate the development of resistant weeds.

49. Furthermore, Dr. Pierson greatly overemphasizes the importance of correct timing for resistance management. That is, even with correct

timing, resistance is likely to develop in some weed species if other more important actions, especially alternation or tank-mixing of other herbicides, are not consistently used. For example, Dr. Pierson, at 43, cites studies by Wilson and Stahlman, and another by Stoltenburg, that no resistance emerged after several years of continuous use of glyphosate in field trials. At 44, Dr. Pierson concludes this section by remarking that after seven years of proper application of roundup, no resistance developed.

50. These examples seem to imply that the "proper use" of glyphosate will prevent resistance from occurring. However, this interpretation of these data is incorrect, and has been strongly criticized by at least 10 highly regarded academic weed scientists (Boerboom, et al., Wisconsin Crop Manager, "Selection of Glyphosate Resistant Weeds," Department of Agronomy - University of Wisconsin-Extension; a true and correct copy is attached as Exhibit E). The gist of the criticism, which I support entirely, is that the sample of weeds exposed to glyphosate in these trials is much too small to accurately indicate whether rare resistance genes occur in the entire geographic range of the weed that would be exposed to glyphosate if it were commercialized. For example, a resistance gene may only occur in 1 in 100,000 or 1 in 1,000,000 plants (genes for resistance are not caused by the herbicide, but already exist at very low frequencies in the weeds. The herbicide merely gives a great advantage to the rare resistant weed by killing off its competition). However, the number of weeds in a field trial is relatively small, and therefore a rare resistance gene may not be present. On the other hand, a rare gene

may very well occur in the many more weeds found throughout the alfalfa-growing regions.

51. Furthermore, email communication between me and Dr. Stolenberg several years ago clearly indicates that he strongly agrees with this interpretation of the data from his experiment, and therefore Dr. Pierson has clearly misapplied these data (Dave Stoltenberg email to Doug Gurian-Sherman, December 21, 2004, a true and correct copy is attached as Exhibit F).

52. Therefore, the studies cited by Dr. Pierson shed no light on the issue of whether "proper use" of the herbicide will prevent resistance. In fact, as I indicated above, so-called proper use will do little to prevent resistance if other measures, not required by Monsanto and APHIS, are not mandated.

53. Dr. Pierson, beginning at para. 48, discusses several other stewardship measures that she claims will result in a low probability of glyphosate resistant weed development. Frequent mowing of the alfalfa is said to be an excellent method of weed control because it prevents weeds from setting seed, and thus spreading resistant progeny. Several mitigating factors can substantially reduce the effectiveness of this practice. First, in areas where winter weeds are important, several such weeds may set seed prior to the first mowing of alfalfa in the spring. Second, some weeds like chickweed can produce flowers and seeds from lateral branches that develop below the mowing level. Third, especially in the first year when the grower is establishing the stand, less frequent mowing may be desired because frequent mowing can weaken the stand. This practice may also be performed to help prolong the useful life of the stand. Fourth, perennial

weeds, such as several important wild grasses and others, can reproduce and spread vegetatively (e.g. by runners), and therefore do not need to set seed to spread resistance. And finally, where alfalfa is grown for seed, the crop must be grown longer without mowing to let the seed develop.

54. At para. 51 Dr. Pierson notes that glyphosate will typically not need to be applied more than once, and that only during the first year, and therefore there will not be much selection for resistance. It is generally agreed that herbicide use is typically most needed in the first year to allow the alfalfa to become established. However, another use that may occur fairly often is use in later years when the stand begins to thin. This latter use will depend on how long the farmer wishes to try to extend the life of his/her alfalfa stand, and also to some extent where the alfalfa is grown.

55. Secondly, Dr. Pierson does not take into account the "seed bank" produced by most weeds. Most weed seeds can survive for several years in the soil before sprouting, a process called dormancy. Therefore, some of the resistant seed selected during applications of glyphosate during the first year can survive until glyphosate is used again several years later.

56. At para. 52, Dr. Pierson notes that Monsanto aggressively investigates possible incidence of resistant weeds. However, in the several instances of glyphosate weed resistance so far reported; this has not been sufficient to eliminate those weeds.

57. In summary, the measures discussed by Monsanto, along with mowing, do little to address the issues that have caused several important weeds to

develop resistance to glyphosate, and in some cases, spread dramatically. Overall, they may reduce the possibility of resistance developing compared to taking no such actions, but the increased use of glyphosate due to adding RR alfalfa to the already commercialized RR crops will increase the probability that glyphosate-resistant weeds will arise.

58. In addition to suggesting that herbicide resistance is not unique to RR crops, Dr. Putnam suggests that Roundup resistance has occurred in conventional (non-RR) crops. He cites glyphosate-resistant ryegrass, claiming that this weed is the most prominent example. Although it is true that glyphosate resistance can occur in non-RR crops, this does not negate the fact that RR crops are the major route for new RR resistant weeds. Furthermore, it is disputable that ryegrass resistance is more prominent than other glyphosate-resistant weeds. For example, resistant horseweed that developed in RR crops, is reported to infest far more acreage than both resistant ryegrass species combined (see http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12). It is noteworthy that at least several cases of glyphosate resistant ryegrass arose in orchards in the US and Australia. Orchards and vineyards are naturally tolerant of glyphosate if kept off the green parts of the trees or vines, so those crops have had the highest use prior to RR crops.

59. Dr. Undersander comments that weeds cannot produce seeds in alfalfa because of frequent mowing. As discussed above, in the case of some important weed species, this is not accurate.

60. Dr. Undersander also comments that multiple generations of seed production are necessary for

resistance to develop. The spread of already resistant weeds can be facilitated, and the frequency of resistance genes can be increased in weeds that are not yet recognized as resistant. Furthermore, for weeds that can spread vegetatively, such as by stolons or rhizomes (i.e., runners), seed production is not needed. The critical factor is that plants carrying the resistance genes increase, and for plants that reproduce vegetatively, this increase can occur without seed. Some extremely important alfalfa weeds such as Johnson grass and crabgrass can spread in this manner.

61. Dr. Undersander further claims that there are no glyphosate resistant weeds in alfalfa. First, we simply do not know if this is the case. As noted above, resistance genes typically exist in weeds at very low frequencies until selected by an herbicide. It is entirely possible that there are weeds infesting alfalfa now that have a glyphosate resistance gene that we simply are unaware of. This is exactly the point of how resistance develops.

Biological Contamination

62. In addition to my other qualifications, I am qualified as an expert on biological contamination. I wrote a recent report on gene flow, and my organization, Union of Concerned Scientists ("UCS"), has authored several reports on contamination and how it can occur. Furthermore, I was a regulatory scientist at US EPA in the group that regulated StarLink, a genetically engineered corn, at the time it was approved and when it contaminated the food supply. StarLink was the most important contamination incident from genetically engineered crops, and we learned much from it, and from the subsequent

Scientific Advisory Panels of independent expert scientists, about contamination and its consequences.

63. For example, in the UCS report, "Gone to Seed," we found that about 50% or more of the certified non-GE corn, canola, and soybean seed has been contaminated with transgenes. The level of contamination was typically 0.05%-1.0%, far greater than the minimum levels that can be detected. It is important to understand that the seed tested for this report was certified, i.e., grown under conditions to ensure varietal purity, as is proposed for RR alfalfa. Yet this seed was widely contaminated by transgenes nonetheless. Although the proposals by APHIS are aimed at foundation purity levels in some cases (somewhat more stringent separation), this would, at best, only reduce somewhat the levels of contamination. Other proposed measures would similarly not prevent contamination at significant levels. A true and correct copy of "Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply," M. Mellon and J. Rissler, 2004, Union of Concerned Scientists, is attached as Exhibit G.

64. An important point that can be taken from "Gone to Seed" is that the frequency and levels of contamination of soybean seed was found to be about as high as for corn. Soybeans are largely self-pollinating (do not pollinate other soybean flowers very often), while corn is highly out-crossing. Therefore, the contamination of soybean seed is likely to be largely from causes other than cross-pollination. Such causes could include seed mixing or human error, and suggests that these sources may be at least as important as cross-pollination.

65. Even based on the gene flow (contamination) data presented by the defendants' experts, levels of contamination many fold higher than can be detected by widely used technology were found (so called polymerase chain reaction, PCR, to detect DNA at levels around 0.01%, or 1 part in 10,000).

66. In a prominent previous contamination incident, StarLink genetically engineered corn, approved by USEPA only for animal feed use, contaminated a large part of the domestic food corn supply, resulting in hundreds of millions of dollars in recalls and other remediation. In that case, the company that owned the corn, Aventis, assured EPA that it could keep it out of the human food supply. It was only grown for about two years before it was detected in corn products in the US. It was also only grown on between about 0.5% and 1.0% of the corn acreage, and despite this, the contamination was widely dispersed in the food supply. The StarLink situation has several parallels with the current situation with RR alfalfa. First, there were concrete plans and assurances that it could be kept out of the food supply. Second, it had been grown for only a short time before contamination occurred, and as little, or less than, the proposed time it may take to complete the EIS for RR alfalfa.

67. In general, the problem is that there are many routes whereby contamination may occur—through cross pollination between GE and non-GE fields, accidental mixing of seeds, contamination of seeds by farm equipment, and human error, being some prominent routes. The methods proposed by APHIS and Monsanto are unlikely to prevent contamination by any of these paths.

68. Another report by Union of Concerned Scientists, ("A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops," David Andow, et al., Union of Concerned Scientists, December 2004, a true and correct copy is attached as Exhibit H) enlisted the assistance of several academic experts in agricultural sciences to determine whether GE pharmaceutical-producing crops could be kept out of food. This report demonstrates how difficult this is, even for pharmaceutical crops that would be grown on much less acreage than alfalfa and under stringent confinement, to avoid contaminating food. The authors of this report examined the types of confinement methods that are proposed by APHIS and Monsanto, such as separation of fields, cleaning of farm equipment, segregation of seed, and others, and found that it would still be difficult to ensure the absence of contamination. The experts felt that contamination might be prevented by taking heroic means, such as geographical isolation from food crops (growing in a region of the country where the non-GE food crops is not grown), but these measure go far beyond the proposals of APHIS and Monsanto. Union of Concerned Scientists concluded that even though it may be theoretically possible to prevent contamination, it would not be economically feasible. It certainly would not be feasible for a widely grown field crop like alfalfa.

69. Another route of contamination that is unpredictable, but likely over time, is human error. Two academic ecologists address this in a peer-reviewed paper, and conclude that contamination by GE crops due to human error or other means has

occurred numerous times, and is likely to continue to occur. This paper documents many instances where GE crops are known to have contaminated non-GE crops or food. (M. Marvier and R. Van Acker, "Can crop transgenes be kept on a leash?" Front. Ecol. Environ., 2005, vol.3, p.95-100, a true and correct copy is attached as Exhibit I).

70. This paper also shows that it is extremely difficult to eliminate widespread contamination by GE crops from the food supply once it occurs. Despite a very large effort and great expense, the StarLink gene continued to be found at low levels in the food supply as of several years after cleanup efforts were begun. Contamination by RR alfalfa that may occur during the preparation of the EIS may be very difficult and costly to eliminate.

71. Since the publication of that paper, a number of other contamination events have occurred. These continue to illustrate how difficult it is to prevent contamination at detectable and economically important levels. Of particular interest is the recent contamination of rice by the unapproved GE LL601. This type of GE rice was grown only in limited-acreage field tests, rather than on a commercial scale, and under the regulatory auspices of APHIS, which includes confinement recommendations. It had not been grown at all for several years, but contamination of the US rice supply was detected several years later at low levels that have nonetheless caused economic harm to the US rice industry. At least one identified source of contamination by LL601 occurred at Louisiana State University (LSU), where one of the scientists in charge has claimed that they exceeded APHIS confinement recommendation considerably, but

still experienced contamination. Provisions taken to prevent contamination were similar or exceed proposals by APHIS and Monsanto. For example, separation from non-GE rice fields was several fold more than APHIS recommends, and proportionately more than the proposed separation for some of the RR alfalfa from non-RR alfalfa. As with the RR alfalfa proposal, LSU said they used segregated facilities and other measure to prevent contamination. (G. Vogel, "Tracing the transatlantic spread of GM rice," Science, 2006, vol. 313, p. 1714, a true and correct copy is attached as Exhibit J). It is much harder to ensure that contamination will not occur from a widely grown commercial GE crop such as RR alfalfa than from a small field test, such as LL601 at LSU, that involved many fewer opportunities for contamination to occur.

72. One route for contamination to occur is when RR alfalfa for hay (the majority of acreage, and of the greatest geographic distribution) is grown near non-RR alfalfa grown for hay or seed. In this case, the RR alfalfa can be grown as close as just over 165 feet from the non-RR counterpart. The declarants give a number of reasons why they believe that this distance is sufficient to prevent significant contamination. However, their arguments are inadequate for several reasons.

73. First, they assert that bees needed to pollinate alfalfa are not stocked in alfalfa grown for hay, and hence RR hay alfalfa will not have bees supplied to it, and will therefore not pollinate nearby non-RR seed alfalfa. However, one of the most common alfalfa pollinators, leafcutter bees, occur in the wild, and therefore may be present in substantial numbers in many areas. Other wild bees may also pollinate alfalfa,

for example, bumble bees are reported to travel five miles or more. Also, honey bees can occur in feral populations (domestic honey bees that have become wild) almost anywhere where alfalfa is grown. These wild populations may or may not be large enough to contaminate non-RR alfalfa to a substantial extent.

74. The defendants also do not even consider that alfalfa growers that produce non-RR seed will stock their own bees to ensure high levels of pollination where needed. These bees will also then visit nearby RR alfalfa fields grown for hay, and transfer pollen back to the seed fields. The defendants suggest that gene flow from a hay field to a seed field will be extremely low based on a single study by Teuber and Fitzpatrick, discussed by Dr. Hoffman in his second declaration page 3 and 4 (also, Hoffman second declaration, attachment #3), where the hayfield achieved 20% - 50% bloom compared to the 10% bloom allowed for RR alfalfa hay. Dr. Hoffman assumes that contamination would be much less due to the 10% bloom limit allowed under the APHIS proposal. However, this assumption cannot be made for several reasons. First, there may not be a significant difference between 20% and 10% bloom. Without experimental data, we cannot know how much contamination difference, if any, the difference in bloom percentage would make.

75. Second, there is substantial variation in the results from different experiments when measuring gene flow (contamination). This has been seen for virtually every crop studied, and is seen when comparing the data of the studies presented by the defendants for alfalfa gene flow. Many factors affect gene flow frequencies, including weather conditions

(precipitation, wind, temperature, humidity), which will affect bee behavior, pollination levels, and the duration of pollen viability. The relative size of the pollen recipient and pollen production fields also has a very big impact on the distances and frequencies of gene flow. As one example, a field trial of creeping bentgrass containing 286 plants revealed contamination at up to about 1400 feet, while one of 400 acres had cross-pollination at 13 miles. (JK. Wipff and C. Fricker, "Gene flow from transgenic creeping bentgrass (Agrostis stolonifera L.) in the Willamette Valley, Oregon," International Turfgrass Society Research Journal, 2001, vol. 9, p. 224-242 and LS Watrud et al., "Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker," 2004, PNAS true and correct copies are attached as Exhibits K and L). Small canola field trials (another bee pollinated crop) often have significant cross pollination at several hundred to several thousand feet, while a study in Australia at the commercial scale observed contamination at up to about 3 kilometers. (MA Rieger et al., "Pollen-mediated movement of herbicide resistance between commercial canola fields," Science, 2002, vol. 296, p. 2386-2388, a true and correct copy is attached as Exhibit M.) Therefore, the data presented are insufficient to allow any general conclusions about contamination levels by gene flow.

76. The importance of the size of both pollen source and pollen capture fields in gene flow experiments is relevant to the results presented by Dr. Teuber in his declaration. For example, in his larger study (Teuber declaration, p. 8, line 3), Dr. Teuber notes that the hay field used as a pollen source was only 1.32 acres. The

very small size of this source field compared to commercial RR alfalfa hay fields, means that gene flow from the larger commercial fields could be considerably higher at longer distances. In any case, even with the relatively small source field, contamination levels up to 0.25% at 150-300 feet are significant and are about 25 fold higher than detection levels.

77. If, however, for the sake of discussion, we reduce the contamination frequencies observed by Teuber and Fitzpatrick in half, assuming a linear decrease in pollination frequency for 10% bloom, we still have frequencies of 0.1%-0.15%, which is about 10-15 times higher than can be reliably detected with common detection technology.

78. Consideration should also be given to the fact that many alfalfa farmers may grow for hay production, and then allow the stand to set seed for future planting or sale at the end of the season. These fields would be subject to contamination as discussed above.

79. Dr. Hoffman then cites other data to support larger isolation distances to protect non-RR seed from contamination from RR alfalfa seed-production fields. The separation distances do not prevent significant contamination by the defendants' own estimation. For example, contamination of 0.1% would be expected based on the presented data for the separation distance for leafcutter (1500 feet) or honeybees (3 miles). Again, this is roughly 10 times higher than detection limits for available technology. In addition, the distances are set based on supplying the field with either leafcutter or honey bees. The required separation distance is much less for leafcutter bees because they forage at shorter distances than do honeybees. However, this separation requirement does not take into account the existence of

feral honeybees, which may be present at fields where the separation is 1500 feet based on the stocking of leafcutter bees.

80. Recent data compiled by the Idaho Alfalfa and Clover Seed Growers Association (IACSGA) shows easily detectable gene flow frequencies, at much greater distances, for alfalfa grown for foundation seed. This raised considerable concern that accepted separation distances (such as the 165 foot distance) are inadequate to prevent considerable contamination from RR alfalfa. The IACSGA specifically expressed concern about RR hay growers contaminating non-RR alfalfa seed fields. For example, contamination of 0.2% was found in a foundation non-RR alfalfa seed field at 7900 feet from the nearest RR alfalfa field. For 10 of 11 sites listed, contamination ranged from 0.2%-0.4% at distances of 900 feet to 1.5 miles, with little dependence on distance. This is about 20 – 40 times higher than the limits of detection with typical sensitive methods. At one site 1400 feet from the RR field, contamination was 0.9%. (Idaho Alfalfa & Clover Seed Association, December, 2006, a true and correct copy is attached as Exhibit N).

81. Research by Bob Hammon examined gene flow from RR alfalfa to feral alfalfa, and found high levels of contamination at considerable distances. Contamination frequencies ranged from 0.18% to 9.46%, the latter at one third mile, or over 1700 feet. There was not a good correspondence between distance and contamination level. (B Hammon et al., "Pollen movement from alfalfa seed production fields," a true and correct copy is attached as Exhibit O).

82. The second declaration of McCaslin at paragraph 13 and Exhibit A, argues that the data of

Hammon do not support significant levels of gene flow from feral RR alfalfa plants into non-RR seed alfalfa. This is mainly because the feral plant populations are typically much smaller than the crop alfalfa plant numbers. Usually, greater gene flow occurs from larger populations of plants to smaller populations, compared to gene flow in the opposite direction.

83. However, the data of Hammon are also useful as a measure of gene flow rates and distances from an RR field to non-RR plants. From that perspective, the data of Hammon shows that high levels of gene flow from RR alfalfa fields are possible at considerable distances that could make the proposed separation distances inadequate. In particular, using the proposed leafcutter bee separation distance of 1500 feet may be grossly inadequate in some cases where feral honeybees are present, or where non-RR growers stock honeybees to pollinate their non-RR seed alfalfa. In Hammon's field experiments, it was noted that they quit collecting leafcutter and honeybees because they were so common.

84. It is also important to note that there were not good correlations between distance and levels of contamination in the Hammon study, and contamination levels did not decline with distance in the data of Teuber and Fitzpatrick cited in the IACSGA data discussed above. This type of result is not uncommon in gene flow studies, especially at longer distances from the pollen source. In fact, the results of Teuber and Fitzpatrick are the rule rather than the exception, where at longer distances, detectable levels of gene flow do not continue to diminish with increasing distance (over the distances examined in the various studies). This counter intuitive result (called a

leptokurtic distribution) means that at low but easily detectable levels, contamination may occur at considerable distance from the RR fields, and beyond the separation distances proposed by APHIS. Dr. Hoffman seems to assume in his second declaration at the top of page 5 that because the proposed separation distances exceed the AOSCA recommended isolation distances, contamination at the longer distances would be negligible. However, Dr. Hoffman's statement does not take into account the typical leptokurtic distribution of gene flow frequencies.

85. My discussion below addresses the point brought up in the second declaration of Dr. Pierson, and the declarations of Drs. Putnam and Undersander.

86. Dr. Pierson cites several studies to support lower levels of gene flow in her second declaration at paragraphs 13 and 14, however, other data already discussed show higher levels. The variability in data is expected because of the different ways the experiments where conducted, and differing environmental conditions at the time. Therefore, we should consider the range of data, and assume that higher levels of contamination at greater distances can occur, as some of the data show.

87. Other considerations mentioned by the declarants that may reduce contamination frequencies from pollen flow are theoretical and do not overturn actual measurements presented in the declarations showing that easily detectable levels of contamination may occur under the restrictions proposed by APHIS and Monsanto.

88. For example, the calculations by Dr. Putnam in his declaration on page 9, lines 21-28, and page 10, lines 1-9 are essentially arbitrary. His 10 fold reduction

factors, as well as the probability that they would apply in any given situation, are entirely unsupported and have no real validity. It is just as likely in any given situation that none of these factors that may reduce contamination would occur.

89. In another example, differences in flowering time between the RR field and non-RR fields are cited (Pierson, second declaration at 17) as a reason that contamination may not occur. Differences in flowering time may occur due to different planting times or use of different alfalfa varieties that flower at different times, by different farmers. However, it is also common for similar varieties to be planted near each other at close to the same time. Furthermore, these same considerations also apply to the previously commercialized GE crops where contamination has been pervasive, as shown in "Gone to Seed". In other words, crops such as corn or soybeans have multiple varieties that flower and may be planted at different times, as well as alfalfa. One factor that may reduce variation in planting time and the alfalfa varieties grown in an area, are that the factors that determine variety and planting schedule will often be the same for neighboring growers. For example, flowering time of the variety may be chosen depending on the length of the growing season, as may planting schedules.

90. While some statements by Dr. Pierson (second declarations, 15-28) about factors that reduce pollination are refuted by actual data, others are simply inaccurate. For example, at 18, Dr. Pierson claims that alfalfa seed producers must stock bees to produce seed. This is untrue if, as is often the case, wild or feral bees are present. It may still be necessary to stock bees to ensure high levels of seed production, but even without

stocking, enough wild bees may be present for considerable pollination.

91. Dr. Putnam also discusses possible impacts on organic growers and possible remedies. For example, on page 11, lines 26-28, Dr. Putnam notes that the National Organic Standards do not recognize specific tolerance levels. However, this ignores the desire of organic consumers and export customers to have products with no detectable GE content.

92. At page 13, lines 17-18, Dr. Putnam notes that it is important for organic growers to begin with non-GE seed. However, this puts expense and burden for testing on growers who are imposed upon by the use RR alfalfa. Suggestions for testing after harvest (Putnam declaration, page 14, lines 11-21) would be of little comfort to a grower whose seed is thereby discovered to be contaminated, and who may loose income because of that fact.

93. Finally, Dr. Putnam notes (declaration, page 15, lines 5-6) that there is a growing demand for non-GE hay. He cites this information to suggest that RR alfalfa has not reduced this demand. However, the issue is not whether RR alfalfa would negatively impact demand for non-GE alfalfa, but rather whether farmers whose alfalfa is contaminated would lose income, and indeed, whether pervasive contamination would reduce the ability of the growing market for non-GE alfalfa to be fulfilled.

94. In summary, the history of GE crops demonstrates that it is probably impossible to prevent contamination of non-GE seed by transgenes with current technology. The data available also strongly suggest that the provisions proposed by APHIS and Monsanto to prevent contamination during the period

of the EIS will not be adequate. They are certainly inadequate to conclude that detectable contamination will not occur. Certainly, the longer a GE crop is commercialized, the more pervasive contamination will become. However, even over the period of the EIS, detectable contamination is likely.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 5, 2007 in Washington D.C.

/s/
Doug Gurian-Sherman, Ph.D

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

JA-707

Weed Science, 49:703-705. 2001

Rapid Publication

Glyphosate-resistant horseweed from Delaware

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No-tillage corn (*Zea mays* L.) and soybean [*Glycine max* (L.) Merr.] production has been widely accepted in the mid-Atlantic region, favoring establishment of horseweed [*Conyza canadensis* (L.) Cronq.]. Within 3 yr of using only glyphosate for weed control in continuous glyphosate-resistant soybeans, glyphosate failed to control horseweed in some fields. Seedlings originating from seed of one population collected in Delaware were grown in the greenhouse and exhibited 8- to 13-fold glyphosate resistance compared with a susceptible population. There were no differences between the isopropylamine or diammonium salts of glyphosate.

Nomenclature: Corn; *Zea mays* L.; horseweed; *Conyza canadensis* (L.) Cronq. ERICA; soybean; *Glycine max* (L.) Merr.; glyphosate.

Key words: Herbicide resistance, glyphosate resistance.

Glyphosate is a broad-spectrum, nonselective herbicide with limited or no soil activity. In recent

years, glyphosate has been used annually in many no-till fields for controlling vegetation prior to planting. Prior to herbicide-resistant crops, glyphosate was applied in combination, or in sequence, with other herbicides that reduced pressure for selection of resistant biotypes. However, with widespread use of glyphosate-resistant soybean [*Glycine max* (L.) Merr.], many no-tillage fields have been treated only with glyphosate. Some of the soils in Delaware are very drought prone and growers have continuously planted soybeans in these fields because they are more drought tolerant than corn (*Zea mays* L.). In 2000, a field treated with 1.6 kg ai ha^{-1} of glyphosate had unaffected horseweed [*Conyza canadensis* (L.) Cronq.] plants next to plants that were completely dead 3 wk after application. The surviving horseweed plants were not controlled with an additional 1.6 kg ha^{-1} of glyphosate.

Previous research has reported naturally occurring glyphosate tolerance in field bindweed (*Convolvulus arvensis* L.) (DeGennaro and Weller 1984; Duncan and Weller 1987). Two Australian populations of rigid ryegrass (*Lolium rigidum* Gaud.) exhibited a 7- to 11-fold resistance to glyphosate, whereas goosegrass [*Eleusine indica* (L.) Gaertn.] in Malaysia had similar levels of glyphosate resistance (Lee and Ngim 2000; Powles et al. 1998; Pratley et al. 1999). In the case of rigid ryegrass, uptake, translocation, or metabolism could not explain the mechanism of resistance (Feng et al. 1999). Glyphosate resistance has not been reported for an annual broadleaf species.

These studies were conducted to confirm glyphosate resistance in a population of horseweed from Delaware. In 1999 and 2000, glyphosate was used exclusively for preplant and in-crop weed control in

glyphosate-resistant soybeans. Prior to 1999, glyphosate was used infrequently for preplant weed control.

Materials and Methods

Horseweed seed was collected at maturity from a soybean field located near Houston, DE, from plants surviving two 1.6 kg ha^{-1} applications of glyphosate. Seeds were also collected from horseweed plants growing at the University of Delaware's Research and Education Center (UD-REC), near Georgetown, DE. The field at UD-REC had not been treated with glyphosate during the past 5 yr and previous glyphosate applications effectively controlled horseweed. Seed from UD-REC served as a susceptible check.

Seeds were planted 0.5-cm deep in commercial potting mix[1] in 9 by 9 by 9 cm pots. Plants were placed in a greenhouse maintained at 28 C and daylength was extended to 15 h using high-pressure sodium lights.[2] Upon emergence, seedlings were thinned to five per pot. Later-emerging plants were removed. Plants were irrigated twice a day and fertilized once, 5 wk after planting, with a commercial fertilizer.[3] Seedlings were treated 3 wk after planting with either the isoproplyamine[4] or diammonium[5] salt of glyphosate at rates of 0, 0.28, 0.56, 0.84, 1.1, 2.2, 4.4, 8.8, or 13.4 kg ai ha^{-1}. Glyphosate was applied with a compressed air cabinet sprayer calibrated to deliver 234 L ha^{-1} at 173 kPa.

The experimental design was a randomized complete block with a three-factor factorial arrangement of treatments. The first factor was biotype, suspected resistant (R) from Houston or susceptible (S) from UD-REC. The second factor was

the glyphosate salt and the third was the glyphosate rate. Each treatment was replicated four times and the experiment was repeated (referred to as Run 1 and Run 2). Replicates were determined by plant size at the time of application. At application, the Houston biotype rosette ranged from 1.5 to 4 cm in diam and the UD-REC biotype ranged from 1 to 3.5 cm for the first run. For the second run, rosette diam ranged from 1 to 3.5 cm and 1 to 3 cm for the Houston and UD-REC biotypes, respectively.

Plants were visually evaluated for percent control at weekly intervals after treatment (0 = no apparent reduction in plant biomass and 100 = dead horseweed). Four weeks after treatment, plants were clipped at the soil surface, dried at 43 C for 4 d, and weighed.

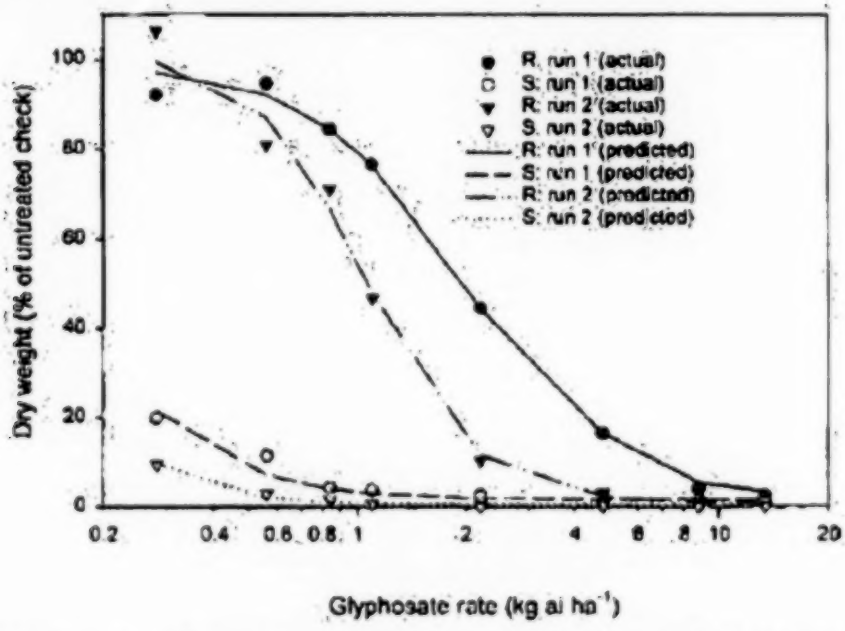

FIGURE 1. Growth response of glyphosate-resistant (R) and susceptible (S) horseweed collected near Houston, DE, and UD-REC near Georgetown, DE, respectively, to various glyphosate rates. Actual and

predicted growth responses for two runs are represented. The predicted line is described by $Y = C + (D - C)/(1 + [x/GR_{50}])^b$ (see text for description of the equation).

Average biomass per plant was expressed as the percentage of the untreated control plants and square root transformation was used to achieve homogeneity of variance. Analysis of variance indicated a significant run by rate interaction; therefore, results are reported by run. Single degree of freedom contrasts were used to determine differences in growth response between the biotypes at each glyphosate use rate. Nonlinear regression parameters were predicted using the log-logistic model, as described by Seefeldt et al. (1995), that relates biomass as the percentage of the control (Y) to the herbicide rate (x):

$$Y = C + \frac{D - C}{1 + (x/GR_{50})^b} \qquad [1]$$

In this equation, C is the lower response limit, D the upper response limit, GR_{50} the herbicide rate that results in a 50% reduction in biomass, and b the slope of the curve around GR_{50}. The level of resistance was determined by calculating an R/S ratio (GR_{50} for the R biotype divided by GR_{50} for the S biotype).

Results and Discussion

The glyphosate salt used was not significant for either run. In addition to different salts, the two commercial glyphosate formulations have different adjuvants that did not influence the results, as can be observed from the lack of significance for main effect and all interactions of glyphosate salt. Horseweed dry weight was described by a sigmoidal function of the

glyphosate rate for both the Houston and UD-REC biotypes.

Both biotypes had similar upper and lower limits as indicated by an *F* test that was not significant. An *F* test comparison of the curves indicates that the slopes were not significantly different for the two biotypes.

Rate by biotype interaction was highly significant for both runs (P = 0.0001) (Figure 1). The interaction indicates that the Houston and UD-REC biotypes responded differently to the same glyphosate rates. Greater than 90% visual control was achieved with 0.84 kg ha^{-1} for the UD-REC biotype, whereas 8.8 kg ha^{-1} was required for the Houston biotype (unpublished data). In the first run, there were differences between the biomass of the two biotypes for glyphosate rates of 0.28 to 2.2 kg ha^{-1} (P = 0.0001) (Figure 1). Differences at 4.4 kg ha^{-1} were significant at P = 0.05. The biotypes had similar biomass at 8.8 and 13.4 kg ha^{-1}. In the second run, differences existed between the biomass of the two biotypes for glyphosate rates of 0.28 to 4.4 kg ha^{-1} (P = 0.0001). Differences for 8.8 and 13.4 kg ha^{-1} were significant at P = 0.1. The cause of the inconsistency between the two runs needs further investigation.

The UD-REC biotype required a glyphosate application of 0.22 and 0.18 kg ha^{-1} to reduce biomass by 50% for Runs 1 and 2, respectively. However, the Houston biotype required 2.8 and 1.4 kg ha^{-1} to achieve a 50% reduction in biomass for Runs 1 and 2, respectively. A 13- and 8-fold difference between the GR_{50} for the two biotypes was determined for the first and second run, respectively. This is similar to the level of glyphosate resistance observed with rigid

ryegrass (Powles et al. 1998; Pratley et al. 1999) and goosegrass (Lee and Ngim 2000).

Increased glyphosate resistance has been achieved through plant breeding for selected grass species and birdsfoot trefoil (*Lotus corniculatus* L.), although not to levels that were commercially acceptable (Boerboom et al. 1991; Johnston and Faulkner 1991; Johnston et al. 1989). Field bindweed selections have been documented to exhibit greater tolerance to glyphosate, although not at the levels reported here. This is the first report of an annual broadleaf plant exhibiting glyphosate resistance caused by repeated glyphosate application under commercial production practices.

Five additional sites in Delaware have shown resistance to glyphosate in greenhouse screening studies (unpublished data). The reproduction, dispersal, and germination ecology for horseweed make it a species likely to infest adjacent and distant fields (Holm et al. 1997; Weaver 2001). This species can grow 1.8 m tall. It produces a large number of small seeds, whose wind dispersal is the most likely means for the spread of resistance between populations. Horseweed seeds are able to germinate and establish in undisturbed soils, providing the potential to colonize no-till fields as well as undisturbed sites. Outcrossing has been documented with horseweed, increasing the potential for spreading the resistant genes both among and between populations. The longevity of the seed in the seedbank has not been determined, yet the seeds remain viable for at least the first 1 to 2 yr following seed shed. Seed longevity increases the difficulty of long-term management of glyphosate-resistant horseweed.

Horseweed responded to the selection pressure from repeated glyphosate application, and the resulting resistance means there are now fewer means of herbicidal control (Polos et al. 1987, 1988; Weaver 2001). Horseweed biotypes have been documented as resistant to various triazines, bipyridyliums, and sulfonylureas.

Future research needs to determine the mechanism of glyphosate resistance in horseweed, as well as the pattern of inheritance. Furthermore, determining the range of the resistant biotypes and better understanding of the resistant and susceptible biotype's biology and ecology is essential for developing effective long-term management strategies.

Sources of Materials

[1] Commercial potting mixture, Premier ProMix BX, Premier Horticultural Inc., 326 Main St., Red Hill, PA 10876.

[2] High-pressure sodium lights, Energy Technics, P.O. Box 3424, 3925 Ridgewood Road, York, PA 17402.

[3] Commercial fertilizer, Miracle-Gro, Scott's Miracle-Gro Products Inc., P.O. Box 888, Port Washington, NY 11050.

[4] Isoproplyamine salt of glyphosate, Roundup Ultra, Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167.

[5] Diammonium salt of glyphosate, Touchdown IQ, Syngenta Crop Protection Inc., P.O. Box 18300, Greensboro, NC 27419.

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Received July 17, 2001, and approved August 14, 2001.

[LOGO OMITTED]

-Weeds-

Selection of Glyphosate-Resistant Weeds

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It is well known that glyphosate-resistant horseweed (also known as marestail) populations have been selected in Roundup Ready soybean and cotton cropping systems. Resistance was first reported in Delaware in 2000, a mere 5 years after the introduction of Roundup Ready soybean. Since that initial report, glyphosate-resistant horseweed is now reported in 12 states and is estimated to affect 1.5 million acres in Tennessee alone.

A person could ask if this is any indication of what might lie ahead. On one hand, it has been proposed in a popular advertisement that glyphosate-resistant weeds are unlikely to occur if glyphosate is frequently used, as long as glyphosate is applied at full rates. The comments in this advertisement, in part, are based on several long-term university studies of Roundup Ready cropping systems. However, the question that a

person should ask about these studies is whether or not they can prove that resistance will or won't happen. It is our belief that these studies are not large enough to test if resistance will develop. For example, the University of Wisconsin has a 7 year Roundup Ready cropping system trial. This trial has horseweed in the no-till plots. Despite burndown and in-crop treatments with glyphosate, glyphosate-resistant horseweed has not developed in these plots. Since this trial did not find glyphosate-resistant horseweed, does this mean that glyphosate-resistant horseweed cannot develop? Does it mean that the resistant horseweed in Ohio or Tennessee or Delaware is not truly resistant? Obviously not. Small scale trials cannot prove that some event will not occur when a larger scale is considered. In total, these Roundup Ready cropping system trials may only be testing continuous glyphosate use on perhaps 50 acres, which is an extremely small fraction relative to total glyphosate. The true real test to determine if a rare event like glyphosate-resistant weeds will develop is actually being tested on the tens of millions of acres of Roundup Ready corn, soybean, and cotton that are sprayed each year.

Many weed scientists across the Midwest have warned of the potential for additional glyphosate-resistant weeds if a "high selection pressure" is maintained. In this case, "high selection pressure" refers to the repeated use of glyphosate without interruption by herbicides with other modes of action or other weed management practices. This potential was confirmed this week at the North Central Weed Science Society Meeting where glyphosate-resistant common ragweed

weed was reported. This is the first report of glyphosate-resistance for common ragweed. It was identified in a Missouri no-till soybean field that has been in continuous soybean production (with some double crop wheat) for many years and in Roundup Ready soybean since 1996. The common ragweed in this field had a high selection pressure for glyphosate with one or more glyphosate applications per year. This is the second example of a glyphosate-resistant weed that has developed in a Roundup Ready cropping system with high selection pressure. We do not know which glyphosate-resistant weed will be the next to develop or when it will occur, but high selection pressure will likely result in additional cases of resistance.

Midwest weed scientists believe in the value that glyphosate and Roundup Ready crops offer to growers. We hope that growers and crop advisors will evaluate how they use glyphosate and the Roundup Ready technologies to gain the value of these technologies without increasing the risk of resistance.

Ideally, we recommend:

- tank mixing glyphosate with another mode of action like 2,4-D in burndown treatments when glyphosate will be applied in the subsequent crop,
- alternating glyphosate use with other herbicide modes of action between years, and
- incorporating appropriate integrated weed management practices such as cultivation.

JA-720

GONE TO SEED
Transgenic Contaminants in the Traditional Seed Supply

[Picture omitted]

[Logo omitted] Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

* * *

MARGARET MELLON
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Union of Concerned Scientists
2004

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Margaret Mellon is the director of the Union of Concerned Scientists Food and Environment Program. Jane Rissler is the deputy director and senior staff scientist of the Union of Concerned Scientists Food and Environment Program.

The Union of Concerned Scientists is a nonprofit partnership of scientists and citizens combining rigorous scientific analysis, innovative policy development, and effective citizen advocacy to achieve practical environmental solutions.

The goal of the Union of Concerned Scientists Food and Environment Program is to create a food system that encourages innovative and environmentally

sustainable ways to produce high-quality, safe, and affordable food, while ensuring that citizens have a voice in how their food is grown.

More information about the Union of Concerned Scientists is available on the UCS website at *www.ucsusa.org*.

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ACKNOWLEDGMENTS

Support for this work was provided by the Beneficial Foundation, C.S. Fund, Deer Creek Foundation, Educational Foundation of America, Eppley Foundation for Research, David B. Gold Foundation, John Merck Fund, Newman's Own, Philanthropic Collaborative, Wallace Genetic Foundation, and UCS members.

The following persons reviewed all or parts of the report at various stages in its preparation: David Andow, Norman Ellstrand, John Fagan, Bill Freese, Molly Jahn, Anne Kapuscinski, Mark Lipson, Marion Nestle, Emily Pullins, Michael Sligh, and Michael Taylor. We appreciate their valuable advice.

Among the many people who helped with the preparation of this report, we extend special thanks to Juanita Mendoza Keesing and Maria Gabriela Silvani for valuable assistance on a variety of tasks associated with the project, Vivienne Woods for help in purchasing seeds, Bryan Wadsworth for copyediting, David Gerratt/NonprofitDesign.com for the cover design and layout, and Heather Tuttle for coordinating print production.

We are grateful to GeneScan USA, Inc., and Biogenetic Services, Inc., for testing seeds and Information Systems for Biotechnology at Virginia Polytechnic Institute and State University for performing special searches of the U.S. Department of Agriculture database on field trials of genetically engineered crops.

We appreciate the support of funders, the valuable advice and information provided by reviewers, and analytical services provided by the testing companies, but we note that this report does not necessarily reflect

their opinions. Willingness to provide financial support, reviews, and testing services does not imply an endorsement of the report or its conclusions and recommendations.

The Union of Concerned Scientists is solely responsible for the contents of this report.

EXECUTIVE SUMMARY

Nothing is more fundamental to agriculture and our food supply than seeds. Whether eaten directly or processed through animals, seeds are the ultimate source of human nutrition. The variety, abundance, and safety of foods are all dependent on the availability and quality of seeds.

The prowess of genetic engineers notwithstanding, seeds cannot be made from scratch. They must be harvested, saved, and shepherded from generation to generation by knowledgeable, engaged individuals. The value to the food supply of the seeds entrusted to our generation cannot be overstated.

In this report, the Union of Concerned Scientists (UCS) examines a new phenomenon that may threaten the quality of the seed supply: the contamination of traditional seeds by DNA sequences derived from genetically engineered crop varieties. These varieties are produced by molecular techniques—variously known as genetic engineering, genetic modification, or transgenic techniques—that allow scientists to move novel traits into plants from distantly related organisms such as animals and bacteria.

The number of transgenes that might potentially contaminate the seed supply is large. Although most commercial transgenic varieties of corn, cotton, soybeans, and canola contain only two traits (herbicide

and insect resistance), hundreds of other novel genes have been engineered into crops that have been field tested but have not been, and may never be, commercialized.

Most of the transgenes used by genetic engineers are new to foods and some are not intended for use in foods at all. For these and other reasons, concerns have arisen about the possibility that transgenes introduced into crop varieties through genetic engineering might unintentionally contaminate the seed supply for traditional, or non-genetically engineered, varieties of crops.

The research covered in this report addresses that possibility with a small pilot study of seeds of traditional varieties of three major food crops: corn, soybeans, and canola. The study found that the seeds of traditional varieties bought from the same retailers used by U.S. farmers are pervasively contaminated with low levels of DNA sequences originating in genetically engineered varieties of those crops.

This conclusion is based on tests conducted by two respected commercial laboratories using duplicate samples of seeds of six traditional varieties each of corn, soybeans, and canola. One laboratory detected transgenically derived DNA in 50 percent of the corn, 50 percent of the soybean, and 100 percent of the traditional canola varieties tested. The other laboratory detected transgenically derived DNA in 83 percent of the traditional varieties of each of the three crops. The most conservative expression of the combined results is that transgenically derived DNA was detected in 50 percent of the corn, 50 percent of the soybean, and 83 percent of the canola varieties tested.

Other than suggesting that the levels are low, the pilot study is too limited to support quantitative estimates of overall contamination levels in seeds of traditional crop varieties. The data available lead us to expect levels of contaminated seed roughly in the range of 0.05 to 1 percent, but larger studies are needed to determine contamination levels with any degree of precision.

In the interim, we are concerned that the significance of low-level contamination might be too quickly dismissed. Contamination levels in the 0.05 to 1 percent range would represent huge absolute amounts of seed. To illustrate, we calculated the tonnage of transgenically contaminated corn seeds that would have been planted in fields of traditional corn varieties if the seed supply were contaminated at a one percent rate. Our calculations, based on U.S. Department of Agriculture (USDA) data on corn acres planted with traditional varieties in 2002, suggest a total of 6,250 tons of transgenically derived seeds—an amount that would fill 240 large tractor-trailer trucks.

Most of the specific DNA sequences for which the laboratories tested are found in popular transgenic crop varieties currently allowed on the U.S. market. Although the study sheds little light on how the seed contamination occurred, there is no reason to believe that the transgenes detected in this study are the only ones moving into the traditional seed supply.

Instead, it seems likely that the contamination is a symptom of generally porous seed production and distribution systems. Until we know otherwise, it seems minimally prudent to assume that novel genes originating in less popular transgenic varieties, as well as the hundreds of engineered varieties that have been

field tested in the United States, could potentially contaminate the seed supply of food and feed crops.

IMPLICATIONS

The recognition that the seed supply is open to contamination by low levels of a wide variety of genetically engineered sequences has broad implications. In general terms, seed contamination is important for two reasons. First, seeds reproduce and carry genes into future generations. Every season of seed production offers new opportunities for the introduction of new genes. In the case of genetic engineering, transgenic sequences that enter the seed supply for traditional crop varieties will be perpetuated and will accumulate over time in plants where they are not expected and could be difficult to control.

Second, seeds are the wellspring of our food system, the base on which we improve crops and the source to which we return when crops fail. Seeds will be our only recourse if the prevailing belief in the safety of genetic engineering proves wrong. Heedlessly allowing the contamination of traditional plant varieties with genetically engineered sequences amounts to a huge wager on our ability to understand a complicated technology that manipulates life at the most elemental level. Unless some part of our seed supply is preserved free of genetically engineered sequences, our ability to change course if genetic engineering goes awry will be severely hampered.

Seed contamination by transgenically derived sequences also has implications in a number of other regulatory and policy contexts. Pharm crops, trade, and organic food production are discussed briefly in this summary, but our report also addresses implications for food safety, the environment,

intellectual property, the food system, and the agriculture of developing countries.

Pharmaceutical and industrial crops receive special attention in this report because the transgenic products they make—drugs, vaccines and industrial chemicals—would raise immediate alarms if they contaminated the food supply, and seed contamination is the back door to the food supply. The realization that seeds for food crops are vulnerable to contamination with pharm and industrial transgenes and that, in fact, some seeds may already have been contaminated is alarming. The report urges prompt action to protect seed production from these sources of contamination.

On the trade front, U.S. grain and oilseed exporters face enormous challenges in a global marketplace bristling with regulatory regimes that apply to genetically engineered crops. U.S. companies need to assure export customers that grain and oilseed shipments do not contain unapproved transgenes and transgenic crop varieties. While gene flow and physical commingling during production and transport probably account for most of the unapproved transgenes and transgenic seed varieties present in exported grain and oilseed, traditional crop varieties carrying transgenically derived sequences may also contribute to the problem. Contamination of the seeds of traditional plant varieties also makes it difficult to supply commodity products free of genetically engineered sequences to those customers who want them.

Transgenic contamination of traditional seed varieties poses a special threat to the future of organic agriculture, an increasingly important sector of U.S.

agriculture. To meet both consumer demand and federal standards that forbid the use of genetically engineered crops and inputs, organic growers strive to produce crops that are free of transgenically derived DNA. If, through no fault of their own, they are unable to supply such products, they potentially face eroding markets. The ease with which the traditional seed supply can be contaminated with transgenically derived DNA unfairly frustrates organics farmers seeking to deliver high-quality products.

RECOMMENDATIONS

UCS hopes that, as a result of this report, the seed and food industries, the scientific community, and the federal government will begin to acknowledge and confront the issues raised by the contamination of the traditional seed supply with sequences originating in genetically engineered crops. While not entirely reversible, this contamination can be substantially reduced. With sufficient attention and will, it is possible to look forward to sources of seeds that are free of genetically engineered sequences. The first step, however, is acknowledging and understanding the problem.

More specifically, UCS recommends the following actions:

1. The USDA should sponsor a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by transgenically derived DNA sequences.
2. The USDA, the Food and Drug Administration, the Environmental Protection Agency, and appropriate coordinating elements of the federal government should amend the regulations for transgenic pharm and industrial crops to ensure

that the seed supply for food and feed crops is not contaminated at any level with drugs, vaccines, plastics, or related substances.

3. The USDA should establish a reservoir of seeds for non-engineered varieties of major food and feed crops free of transgenically derived sequences.
4. The USDA and land-grant (agricultural) universities should reinvigorate the public plant breeding establishment to help ensure a supply of pure seed of traditional crop varieties.
5. The Association of Official Seed Certifying Agencies should establish a national standard for breeder and foundation seed of traditional crop varieties: no detectable level of contamination by transgenes and associated sequences originating in genetically engineered crops.
6. The USDA, the organic agriculture community, land-grant universities, and plant breeders should develop new policies and programs to provide organic agriculture with pure seeds of traditional crop varieties.
7. The USDA, the organic and biotechnology industries, and national growers' associations, among others, should sponsor a series of meetings to begin addressing how those sectors of U.S. agriculture that have adopted transgenic crops and those threatened by contamination with transgenically derived DNA sequences from those crops can coexist.
8. Private seed companies in the United States should periodically test their seed stocks, especially breeder and foundation seed and

parental inbred lines, for the presence of transgenically derived DNA sequences. They should then make public the extent to which the seeds of the traditional varieties they market are free of transgenically derived contaminants.

Chapter 1

INTRODUCTION

This report describes the results of a pilot study designed to address the extent to which genetic elements introduced into the crop gene pool via genetic engineering are now present in crop varieties with no history of genetic engineering. The results suggest that seeds representing a wide array of corn, soybean, and canola varieties currently on the market commonly contain identifiable genetic material originating from transgenic crop varieties.

The varieties collected for analysis in this study were produced by traditional, field-based plant breeding techniques. These techniques rely on identifying and mating parent plants that possess promising traits and repeatedly selecting for superior performance among their offspring. Seeds for offspring that do well in performance trials are then increased prior to sale as a commercial crop variety. Traditional plant breeding, a potent technology often taken for granted, is largely responsible for the tremendous gains in productivity of global agriculture during the twentieth century. (See Figure 1-1, p. 8, and Appendix A for more information on variety development and seed production.)

The sources of the novel genetic elements that now appear to contaminate the seed supply of traditionally bred crop varieties are varieties created by newer

molecular-level laboratory techniques. These techniques, collectively known as genetic engineering, allow scientists to insert and express genetic material originating in organisms unrelated to the crops in question.

Unlike traditional breeding methods that rely on mating between male and female parents to generate new or improved traits, laboratory-based techniques can move genetic material directly into plants from organisms as distantly related as bacteria or animals. These techniques are also referred to as genetically modified or transgenic. The organisms produced by these techniques are referred to as genetically engineered organisms, genetically modified organisms (GMOs), and transgenics.

In this report, we will refer to crop varieties with no history of genetic engineering as traditional varieties and the seeds for those varieties as traditional seeds or the traditional seed supply. Crop varieties produced via genetic engineering techniques are described as transgenic, although we recognize that field-based techniques used to develop traditional varieties are also used in the production of commercial transgenic varieties. Transgenic seeds or the transgenic seed supply refers to seeds used to grow transgenic crop varieties.

The DNA sequences introduced into plants during the genetic engineering process are referred to as transgenically derived or transgenic sequences, and novel genes transferred to crops using genetic engineering techniques are referred to as transgenes. Biochemical techniques that make it possible to identify specific DNA sequences, even at very low levels, were critical to conducting this study.

GENETIC ENGINEERING IN AGRICULTURE

Genetic engineering has been a controversial technology from the beginning, especially in Europe and other countries outside the United States. Concerns about the use of the technology in agriculture have focused on a tangle of issues ranging from concerns about food and feed safety to environmental risk and corporate control of the food system.

In theory, genetic engineering can modify plants to produce a wide range of new traits. Yet most engineered varieties commercially planted in the United States and around the world have been modified to express only two narrow categories of traits: resistance to a particular herbicide (thus permitting the use of that herbicide) or the expression of a pesticidal toxin derived from the soil bacterium *Bacillus thuringiensis* (Bt). These are referred to as herbicide-resistant and insect-resistant (or Bt) varieties, respectively.[1]

Bt and herbicide-resistant versions of major crops were first planted on a large scale in 1996 and have been widely adopted in the United States during the last few years.[2] In 2002, for example, about three-

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1 Union of Concerned Scientists (UCS). 2002. Genetically Engineered Foods Allowed on the Market. Cambridge, MA: UCS. On the UCS website at *http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageid=337*, accessed on August 13, 2003. Several herbicide-resistant and Bt varieties are on the market in the United States, including canola, corn, and soybeans resistant to glufosinate and glyphosate herbicides; cotton resistant to glyphosate and bromoxynil herbicides; and Bt corn and Bt cotton.

2 For information on the growth in acreage of genetically engineered crops in the United States and elsewhere, see International Service for the Acquisition of Agri-biotech

fourths of U.S. soybean acres, one- third of U.S. corn acres,[3] and nearly 70 percent of North Dakota's canola acres[4] were planted with engineered varieties. (North Dakota accounts for 89 percent of U.S. canola production.[5]) Traditional, or non-engineered, crop varieties nevertheless remain popular as well, and U.S. farmers continue to plant them in large quantities.[6]

In addition to the handful of transgenes present in commercial varieties of herbicide-resistant and Bt crops, hundreds of other transgenes have been engineered into crops. These varieties, though not yet commercialized, have been field tested in the open environment. Appendix B of this report contains a list of transgenes and transgenic traits taken from a database of U.S. Department of Agriculture (USDA)

Applications (ISAAA) Briefs an the ISAAA website at *http://www.isaaa.org*.

3 U.S. Department of Agriculture, National Agricultural Statistics Service (USDA NASS). 2003. Prospective Plantings. March 23, pp. 20, 21 on the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bbp/pspl0303.pdf*, accessed on August 15, 2003.

4 Berglund, D.R. 2003. Personal communication, August 15. D.R. Berglund is a professor and extension agronomist at North Dakota State University. According to Dr. Berglund, approximately 900,000 of North Dakota's 1,300,000 acres of canola were planted with engineered varieties in 2002.

5 USDA NASS. 2003. Crop Production: 2002 Summary. Publication CrPr2-1(03). p. 31. On the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bban/cropan03.pdf*, accessed on November 25, 2003.

6 Traditional crop varieties remain popular far a number of reasons, including the large international markets for such varieties, the relatively high price of seeds for engineered varieties, and personal preferences.

records of field tests of corn, soybeans, and canola over the past 16 years.[7]

Because transgenic and traditional varieties of major crops are both planted widely and moved together through the U.S. grain distribution system, there are many activities that can mix the two kinds of crops. Most of the commercial bulk oilseeds and grains in the United States, for instance, are now a mixture of engineered and non-engineered seeds. As discussed below, this high degree of commingling has made it difficult for the United States to segregate and deliver a non-genetically engineered product for customers who demand it.

THE CURRENT SITUATION

This study is the first systematic attempt to examine a part of the contamination issue that so far has received little attention: the extent to which the *traditional seed supply* for commodity crops has become contaminated with genetic sequences originating from transgenic varieties.

We use the term "contamination" here to refer to seeds or genetic sequences that are unwanted in a particular place for one reason or another. Corn, for example, is unwanted in shipments of soybeans and in such shipments is properly called a contaminant. The term has no negative connotation other than the sense that a particular entity is for some reason unwanted or inappropriate where it is found.

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7 Information Systems for Biotechnology (ISB). 2003. Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/cfdocs/fieldtests1.cfm*, accessed on December 15, 2003.

"Adventitious presence," another term sometimes heard in this context, connotes a lack of intention in allowing commingling to occur. Adventitious presence in our view is a broader term than contamination. Contamination refers to those situations where genes or traits are not only unintended (or adventitious) but also for some reason unwanted.

Both commercial and legal considerations make the presence of transgenically derived sequences in agricultural products problematic. Many transgenic varieties of crops in use in the United States have not been approved in other countries and their presence in imports is unlawful. In addition, many customers for U.S. exports—particularly those looking to purchase organic food or non-organic specialty products—are exhibiting a strong preference for non-genetically engineered grains and oilseeds free of some or all transgenic varieties.

Many of these customers are rejecting grains and oilseeds containing detectable levels of transgenic varieties regardless of whether the levels or kinds of transgenic varieties render the product technically illegal. In both legal and commercial contexts, the unwanted presence of genetically modified grains or oilseeds, and sequences deriving from them, are therefore properly considered contaminants.

Seeds in commodity agriculture

Each season, farmers plant seeds of commodity crops such as corn, canola, and soybeans to produce a crop that will be harvested and sold as bulk grain and oilseed. Figure 1-1 (p. 8) illustrates how seeds of corn, soybean, and canola varieties move through the agricultural commodity system. For a more

detailed account of crop variety development and seed production, see Appendix A.

Plant breeders are constantly producing new varieties of corn, soybeans, and canola. Every year a set of varieties (old and new) is selected for commercial development and a process called seed increase is set in motion to generate sufficient quantities of seeds to be offered for sale to growers. Seed increase usually requires several rounds of planting and harvesting to meet commercial demands.

For economic reasons, seeds are grown under progressively less stringent containment conditions, which correspond to four classes of seed purity. Breeder seed, controlled by the plant breeding institution, is the purest class of seed, followed by foundation, registered, and certified seed (the least pure class). Private certifying agencies set crop-specific purity standards for each seed class. Examples of corn, soybean, and canola seed standards can be found in Appendix A.

Farmers can obtain commercial seed through retail seed stores, the Internet, and catalogs. Seeds purchased by growers are planted, the plants are tended during the growing season, and seeds are harvested and sold as bulk grain and oilseed products. Eventually these products make their way to end users for a variety of purposes including feed, food, and industrial uses. Substantial quantities of U.S. grain and oilseeds are exported to other countries. Although rarely done in the case of corn, farmers may also retain

soybean or canola seed from their harvest to plant the following year.

[Figure 1-1 Omitted]

SEED VS. BULK CROP CONTAMINATION

As mentioned above, seed contamination, the focus of this report, is only one source of the contamination that bedevils exporters of non-engineered bulk grain and oilseeds.

Most contamination is attributable to events that occur *after the engineered and non-engineered varieties of seed are planted* (Figure 1-1). There are two types of mixing events that occur after planting: physical mixing, such as commingling in grain elevators; and outcrossing, the movement of genes via pollen into neighboring fields of sexually compatible crops. Since both of these phenomena are difficult to control under the current systems of grain and oilseed production, transport, and storage, mixing would occur even if the seeds farmers planted were absolutely free of transgenically derived sequences. While starting with seed contaminated with transgenically derived sequences exacerbates these problems, pure seed would not alleviate them.

EARLY WARNINGS

When transgenic varieties were first allowed on the market in the United States, little attention was paid to the idea that widespread adoption of transgenic crops could lead to seed contamination of traditional varieties. In retrospect, this seems surprising. Breeders working with genetically engineered varieties continued to use the same seed purity standards that applied to traditional varieties. Those standards vary from crop to crop but allow, in the case of soybeans, for example, up to 0.6 percent of the seeds

to come from other kinds of crops such as corn and up to 0.5 percent from other varieties of soybeans (Appendix A). Application of these standards made it almost inevitable that substantial cross contamination would follow the widespread adoption of genetically engineered crop varieties.

A number of factors—among them, the growing global controversy over biotechnology crops, the increasing popularity of organic foods, and regulatory regimes that vary from country to country—have led to demands for crops of far greater purity than the seed production system was geared to deliver. But awareness of this situation emerged slowly. Plant breeders, growers, and others in the agricultural establishment seemed to proceed on the assumption that even as the adoption rates of genetically engineered varieties increased, those who wanted to purchase seed free of transgenic components would be able to continue doing so.

A number of instances of seed contamination over the last seven years have called that optimistic assumption into question.

StarLink-contaminated hybrid corn seed

StarLink was an engineered corn variety approved by the U.S. government in 1997 for use in animal feed but not in human food. In September 2000, after newspapers reported that StarLink corn was showing up in consumer products, the government undertook comprehensive testing of corn-derived foods in the U.S. food supply.[8] Although planted on only 350,000 of the

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[8] Taylor, M.R. and J.S. Tick. 2003. Post Market Oversight of Biotech Foods: Is the System Prepared? Washington, DC.; Pew Initiative on Food and Biotechnology, pp. 90-105

80 million total U.S. corn acres (about 0.4 percent) in its most popular year,[9] genetic sequences from StarLink corn varieties were eventually detected in numerous consumer products distributed throughout the U.S. food supply and in exported corn.

By 2001, StarLink also contaminated the U.S. corn seed supply. Fearing recurrent introduction of the illegal contaminant into food via the seed supply, the USDA instituted a program to buy up corn seed that tested positive for StarLink. In June 2001, the department announced that it had already purchased $13 million worth of StarLink-contaminated seed from 63 companies and was considering additional expenditures of up to $5 million.[10]

Despite concerted effort, it has proved surprisingly difficult to purge the U.S. grain system of the contaminant. As recently as December 2003, StarLink was still being reported in domestic grain.[11] Part of the explanation may be that the seed supply for corn is

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9 Keller, D. and D. Miller. 2000. Biotech's black eye. *Progressive Farmer* (December), p. 24; USDA NASS. No date. U.S. corn acres. On the USDA NASS website at *http://www.usda.gov/nass/aggraphs/cornac.htm*, accessed on December 2, 2003.

10 USDA. 2001. USDA purchases Cry9C affected corn seed from seed companies. Press release, June 15, 2001. On the USDA website at *http://www.usda.gov/news/releases/2001/06/0101.htm*, accessed on November 14, 2003.

11 Fabi, R. 2002. Global updates: Exporters say Japan finds StarLink in U.S. corn cargo. Reuters, December 28; Jacobs, P. 2003. Banished biotech corn not gone yet: traces raise health, other key issues. *San Jose Mercury News* (December 1). On the *Mercury News* website at *http://www.bayarea.com/mld/mercurynews/business/7386106.htm*, accessed on December 2, 2003.

still contaminated. It may be that inbred lines remain contaminated with StarLink genetic sequences and every time these inbreds are used to produce hybrid corn seed, the StarLink sequences are reintroduced into the seed supply. (See Appendix A for details on hybrid corn seed production.)

Contaminated foundation soybean seed

In 2002, the head of North Dakota State University's Foundation Seedstocks Program acknowledged that the program's foundation seed for non-engineered natto soybeans—the basic stock from which seeds are grown to sell to farmers—contained sequences from engineered soybeans.[12] (Natto soybeans are grown for premium food-grade products.) Three other foundation soybean seed programs—in Virginia, Missouri, and Michigan—have also recently reported genetic engineering contamination problems.[13]

Contaminated canola seed

In 1997, Monsanto, a leading biotechnology company, recalled 60,000 bags of seeds of one of its transgenic canola varieties in Canada because they were contaminated with seeds of another transgenic canola variety (RT-200), which had not been approved

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12 Pates, M. 2002. Seed contamination raises control issues, posted November 12, 2002. On the *Grand Forks Herald* website at *http://www.grandforks.com*, accessed on January 7, 2003. The article identified Monsanto's Roundup Ready soybeans as the source of contamination.

13 The *Non-GMO Source*. 2003. Concerns increase over GMO contamination of foundation seed. Volume 3, Number 6, pp. 1-2, June.

for marketing in that country.[14] Four years later, Monsanto detected the RT-200 contaminant again in seeds of commercial transgenic canola varieties in Canada. Even though RT-200 varieties had gained approval in Canada by that time, Monsanto withdrew the contaminated seeds from the market because the contaminating varieties had not been approved in all countries to which Canadian canola would be exported.[15]

Monsanto admitted in 2002 that RT-200 seeds might also have been contaminating U.S. canola seed supplies since 1999. Even though the company has no plans to commercialize RT-200 in the United States, it sought approval of the variety in this country that year to minimize the disruption caused by its contamination of other canola varieties.[16]

In the spring of 2000, Advanta Seeds UK acknowledged that traditional canola varieties contaminated with an engineered variety (GT-73) had been sold to several European Union (EU) countries—where it had not been approved for sale—in 1999 and 2000.[17] In 2002, Scottish scientists discovered that

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14 Rance, L. 1997. Registration suspended: Genetic mixup prompts recall of Roundup Ready canola. *Manitoba Co-Operator* (April 24).

15 Monsanto. 2001. Press statement: Quest canola seed replacement offered, April 25. On the Monsanto website at *http://www.monsanto.com/monsanto/media/01/01apr25_quest.htm*, accessed on December 18, 2001.

16 Hesman, T. 2002. Monsanto says gene-altered food may be in U.S. food. *St. Louis Post-Dispatch* (Business, April 16); Kilman, S. and J. Carroll. 2002. Monsanto admits unapproved seed may be in crops. *Wall Street Journal* (April 15).

17 Brown, N. 2000. Statement of the United Kingdom Minister of Agriculture, Fisheries and Food in the House of Commons,

transgenic canola plants being tested in field trials were contaminated with a transgene not approved for testing in the United Kingdom.[18]

Organic producers struggle to find non-engineered seed

Organic food and fiber is one of the fastest-growing sectors in U.S. agriculture. Not only do many consumers expect organic food to be free of genetically engineered material, but federal standards also forbid the use of genetically engineered varieties in the production of organic foods. Organic growers seeking to meet this standard are finding it increasingly difficult to obtain non-engineered seed. Almost half the organic growers surveyed recently felt that contaminated seeds (rather than post-planting pollen drift, for example) represented the greatest source of contamination from engineered varieties.[19] The difficulty in producing pure seed has led some organic

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May 18. On the United Kingdom Parliament website at *http://www.publications.parliament.uk/pa/cm199900/cmhansrd/vo000518/debtext/00518-09.htm*, accessed on June 18, 2003.

[18] Kelbie, P. and M. Woolf. 2002. Ministers suspend GM crop-testing. *The Independent* (August 16). Obtained from the *biotech_activists@iatp.org* mailing list server August 16, 2002, where the source was listed as *The Independent* website at *http://news.independent.co.uk/uk/environment/story.jsp?story=324776*. Apparently, the contaminated seeds, provided by Aventis (a biotechnology company now owned by Bayer Crop Science), had been planted in more than 20 test plots over a three-year period in England and Scotland.

[19] Organic Farming Research Foundation (OFRF). 2003. Preliminary results from OFRF's fourth national organic farmers' survey: Section 7—GMOs and organic. On the OFRF website at *http://www.ofrf.org/press/releases/pr.051403.gmosurvey.html*, accessed on June 19, 2003.

seed companies to move their seed operations outside the United States.[20]

GOVERNMENT'S FAILURE TO RESPOND

While any one of these incidents might reflect an isolated example of seed contamination, taken together they reasonably suggest a more widespread phenomenon. The prospect of broad contamination of the seed supply raises important questions for food safety, international trade, organic agriculture, and the integrity of the seed system at the base of our global food supply.

The growing evidence of seed contamination should have prompted the U.S. government to determine the extent to which seeds marketed as non-engineered are currently contaminated with engineered sequences. Indeed, the Union of Concerned Scientists (UCS) and others in the public interest community have suggested the government undertake such a study. But it has not responded.

So, UCS decided to conduct a pilot study of its own to assess the extent of contamination in the U.S. traditional seed supply. These seeds, along with seeds for transgenic varieties, are available from seed retailers, by mail order, and over the Internet.

As described below, our study found low levels of transgenically derived sequences in most of the samples of non-engineered corn, canola, and soybean seeds that we tested. The samples were obtained from seed sold in a number of locations around the United States. Our results suggest that the U.S. supply of

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[20] *The Non-GMO Source*. 2003. Organic seed company moves corn production to Argentina to avoid GMOs. Volume 3, Number 1, p. 3, January.

seed for traditional varieties of corn, soybeans, and canola is pervasively contaminated with low levels of genetic sequences originating in transgenic varieties.

IDENTITY-PRESERVATION SYSTEMS

The purity of seed is an issue of growing interest outside the arena of genetic engineering. New efforts are under way to create value-added markets for high-value crops, including some produced by genetic engineering. High-value crops exhibit desirable traits such as increased levels of important nutrients or the ability to produce a drug or industrial chemical. Today's commodity system, which minimizes transportation, cleaning, and handling costs in part by tolerating a relatively high degree of cross-contamination, cannot meet the need for segregated, pure supplies of these high-value crops.

Spurred by market demand, individuals and companies are taking on the challenge of developing new infrastructure and delivery systems for value-added products.[21] New "identity-preserved" systems create alternative pathways between seed suppliers, growers, and customers that avoid the current commodity system and its endemic sources of cross-contamination.[22]

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21 It is important to note that these systems are designed to respond to commercial, not safety, considerations.

22 Strayer, D. 2002. *Identity-Preserved Systems: A Reference Handbook*. Boca Raton, FL: CRC Press; Sundstrom, F.J., J. Williams, A. Van Deynze, and K.J. Bradford. 2002. Identity Preservation of Agricultural Commodities. Agricultural Biotechnology in California Series, Publication 8077. Davis, CA: University of California, Davis. On the UC Davis website at *http://anrcatalog.ucdavis.edu*, accessed on May 30, 2003.

The U.S. government is currently exploring ways to facilitate the marketing of identity-preserved products. For example, the USDA is considering ways to reconfigure the commodity grain system to make segregation more feasible.[23] Fundamental to the new systems devised to "preserve identity" is the ability to produce and preserve the purity of seed.

REPORT OUTLINE

Chapter 2 describes how we conducted our seed study and what we found. Our analysis suggests that the contamination of commercial seed stocks is pervasive and ongoing, and that the current regulatory regimes, which were not designed to prevent such contamination, are incapable of doing so. Because seed stocks are fundamental to agriculture and the food supply, seed contamination has potential implications in a number of arenas. It is time to understand and address these implications.

We have attempted to initiate a discussion of these issues in Chapter 3, where we consider the implications of contamination in nine contexts. The most urgent of these is what many in agriculture expect to be the next big wave of biotechnology applications: crops that produce pharmaceuticals and industrial chemicals. Other contexts include food safety, the environment,

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[23] USDA, Grain Inspection, Packers and Stockyards Administration (GIPSA). 2000. Request for public comments on how USDA can best facilitate the marketing of grains, oilseeds, fruits, vegetables, and nuts in today's evolving marketplace. *Federal Register* 65:21272-21273 (November 30); USDA GIPSA. 2002. Facilitating the marketing of U.S. agricultural products with new testing and process verification services. *Federal Register* 67:50853-50854 (August 6).

trade, organic food production, intellectual property, the food system, agriculture of developing countries, and seed repository integrity.

In Chapter 4, we present our conclusions and recommendations for further research and new policies.

The main text of the report is followed by a glossary and two appendices. Appendix A provides an overview of plant breeding and seed production. Appendix B lists transgenes and transgenic traits engineered into corn, soybeans, and canola for field testing purposes since 1987.

Chapter 2

METHODS AND RESULTS

UCS's pilot study looked at the contamination of the traditional seed supply in three major commodity crops: corn, soybeans, and canola. The seeds tested were selected from the pool of seeds marketed by major seed companies in 2002 to growers in key agricultural states. Selection procedures were developed to ensure that, to the degree possible given our limited resources, the seeds tested were representative of a large portion of the traditional seed supply for these crops.

This chapter describes the study, its results, and its limitations. Text boxes explain the basics of plant genetic engineering and designations used in the text and tables. A glossary is found at the end of the report.

METHODS

Choosing crops

In late 2001, there were 11 crops that had cleared the regulatory hurdles for marketing in the United

States.[24] Among these, only four had engineered versions that had been widely planted: canola, corn, cotton, and soybeans. We eliminated cotton because it is not used primarily for food.

Choosing varieties

The next step was to decide, given limited resources, how to sample the available seeds. To sample as large a portion of the 2002 seed supply as possible, we selected from the pool of non-engineered varieties offered by major seed companies to growers in states that have significant acreage dedicated to the three crops.

For corn and soybeans, specifically, we selected varieties from among those recommended by major seed companies to growers in Iowa and Illinois, the states with the most acreage dedicated to those two crops.[25] From the websites of four major seed companies, we obtained lists of traditional varieties recommended for various counties or zip codes in Iowa and Illinois.[26] We chose to focus on one county in each

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[24] Union of Concerned Scientists (UCS). 2002. Genetically Engineered Foods Allowed on the Market. On the UCS website at *http://www.ucsusa.org/food_and_environment/biotechnology/page.cfm?pageid=337*, accessed on August 13, 2003. The 11 crops allowed on the market were canola, corn, cotton, flax, papaya, potato, radicchio, soybean, squash, sugar beet, and tomato.

[25] According to USDA National Agricultural Statistics Service (USDA NASS) data, Iowa and Illinois planted more acres with corn and soybeans than any other states in the 2002 growing season (*http://www.usda.gov/nass/aggraphs/cornacm.htm* and *http://www.usda.gov/nass/aggraphs/soyacm.htm*, accessed on May 15, 2003).

[26] Major seed companies maintain websites where farmers can find the varieties recommended for their area by entering

state—Polk in Iowa and Wabash in Illinois. Seed companies recommended anywhere from 2 to 40 traditional seed varieties for those two counties (or zip codes within them), and we chose two from each of three companies. That gave us six varieties of corn and six of soybeans.

Where a company recommended more than two varieties for one of those locations, we randomly selected two for testing (Table 2-1). Many of the chosen varieties were recommended for other locations in Iowa or Illinois and other states. We deemed it impracticable to try to determine which varieties were the most widely recommended.[27]

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either their county name or zip code. Between December 2001 and February 2002, we obtained lists of recommended varieties for the 2002 growing season in Illinois (Wabash County; zip code 62806) and Iowa (Polk County; zip code 50011) from the following seed companies' websites: Monsanto/Asgrow at *http://www.farmsource.com*, Syngenta at *http://www.nk-us.com*, DuPont/Pioneer at *http://www.pioneer.com*, and Dow/Mycogen at *http://www.mycogen.com*.

27 Company websites are set up in such a way that it is difficult to determine how widely a particular variety is recommended. To do so would require searching for varieties recommended in every crop-growing county or zip code in the country.

TABLE 2-1 Traditional Varieties of Corn, Soybeans, and Canola Selected for This Study

Crop	Company Producing Seeds of Traditional Varieties	Seeds of Traditional Varieties Purchased		
		Variety Designation Used in This Report	Company Variety Designation*	From a Seed Retailer In:
Corn	DuPont/ Pioneer	1	36B08	Clarke County, VA
		2	34G13	Clarke County, VA
	Syngenta	3	N60-N2	Edwards County, IL
		4	V72-V7	Frederick County, VA
	Dow/ Mycogen	5	5212	Frederick County, VA
		6	2A791	Frederick County, VA
Soybean	DuPont/ Pioneer	7	94B53	Edwards County, IL

Crop	Company Producing Seeds of Traditional Varieties	Seeds of Traditional Varieties Purchased		
		Variety Designation Used in This Report	Company Variety Designation*	From a Seed Retailer In:
		8	93B82	Clarke County, VA
Soybean	Syngenta	9	S25-J5	Edwards County, IL
		10	S42-H1	Edwards County, IL
	Monsanto /Asrow	11	A2869	Edwards County, IL
		12	A4922	Jefferson County, WV
	Proseed	13	Top-Score	Wells County, ND
		14	Canterra 1492	Wells County, ND
Canola	Interstate	15	Hyola 330	Cass County, ND

Crop	Company Producing Seeds of Traditional Varieties	Seeds of Traditional Varieties Purchased		
		Variety Designation Used in This Report	Company Variety Designation*	From a Seed Retailer In:
		16	Hyola 401	Cass County, ND
	DuPont/ Pioneer	17	46A65	Lake County, MT
		18	46A76	Lake County, MT

* Company seed lot designations available upon request.

For canola, we adopted a slightly different approach, focusing on varieties offered to growers in North Dakota, which accounted for 89 percent of U.S. canola acreage in 2002.[28] Seed companies' websites did not provide specific recommendations for that state, but North Dakota State University provided data on 2001 performance trials of 33 traditional canola varieties. Using these data, we selected five non-engineered varieties from three companies that

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[28] USDA NASS. 2003. Crop Production: 2002 Summary. Publication CrPr2-1(03), p. 31. On the USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bban/cropan03.pdf*, accessed on November 25, 2003.

performed well in the trials[29] (Table 2-1). Assuming that seeds of better-performing varieties would make up a larger proportion of the seed supply than poorly performing varieties, we believe this strategy allowed us to look at a representative sample of a substantial portion of the non-engineered canola seed supply. Because of difficulties in finding seed of the better-performing varieties, we selected one variety (Topscore) that was not part of the 2001 variety trials.

Basics of plant genetic engineering

Genes are functional segments of DNA located on chromosomes within the cells of organisms, including plants. An organism's DNA, comprised of thousands of genes, forms the blueprint for its inherited traits. The full set of genes and associated DNA of an organism is referred to as its **genome**.

Genes code for **proteins**,* the building blocks of organisms. Proteins, working alone or in combination, are responsible for the traits exhibited by plants (e.g., height, flower color, drought tolerance, insect resistance, nutritional makeup). **Regulatory sequences** control the process by which plant cells manufacture

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[29] Like many land-grant universities, North Dakota State University (NDSU) provides information to state growers on the performance of crop varieties as an aid in choosing which varieties to plant. An NDSU Extension Service publication provided data on 33 traditional varieties tested in variety trials in 2001. (NDSU. 2002. 2001 Canola Variety Trials. NDSU Extension Service publication A-1124 [revised], compiled by Duane R. Berglund. Fargo, ND: NDSU, January, p. 1.)

proteins. For example, **promoters** are regulatory sequences that operate like switches to start the manufacturing process for a particular protein. They also determine the amount of protein produced. **Genetic sequences** or **elements** refer to genes, regulatory sequences, or pieces thereof.

Genetic engineering involves the use of sophisticated molecular methods to synthesize novel combinations of regulatory sequences and genes and transfer them into an organism. These techniques may be used to transfer genetic sequences between unrelated organisms—from soil bacteria to a corn plant, for example—or to remove and rearrange genetic sequences within a species. Applying these techniques to crops, scientists create crop varieties with new traits. Various terms are used to describe plants produced by these techniques: **genetically engineered, genetically modified**, or **transgenic**.

A variety is a subgroup of plants within a crop whose genetic makeup and agricultural characteristics distinguish it from other varieties of that crop. Seed companies are constantly developing new varieties with traits important to growers, such as higher yield or increased resistance to insects and herbicides. These traits may be obtained through genetic engineering or traditional breeding.

To introduce a new trait through genetic engineering, scientists first assemble a **construct**, which can be visualized as a cassette of genetic sequences often taken from several

different organisms. Constructs typically carry several regulatory sequences and genes.

After all the pieces of DNA are joined together, the construct is inserted as a unit into an individual plant, creating what scientists refer to as a **transformation event**, or **event** for short. Companies often use the same designation, such as GTS 40-3-2, for both the construct and the plant (and its progeny) created with that construct. A list of events relevant to this report is included below.

As a first step, scientists typically insert new constructs into plant varieties that are easily engineered. Transferring the new event into agronomically valuable varieties is accomplished by **traditional plant breeding**.

The diagrams to the right illustrate a generalized construct and a specific construct used to produce soybean varieties resistant to glyphosate herbicides,

GTS 40-3-2 is a construct developed by Monsanto to create Roundup Ready soybeans, which are resistant to the company's glyphosate (Roundup) herbicides. The construct contains a gene coding for a protein and three regulatory sequences: a promoter, a terminator, and a chloroplast transit peptide that directs the new protein to chloroplasts, where it functions in a particular metabolic pathway.

**Some scientists use the term gene to encompass the DNA sequences coding for regulatory sequences as well as proteins.*

Genetically Engineered Transformation Events

Event	Trade Name	Crop	Company	Trait
176	KnockOut NaturGard	Corn	Syngenta Dow/Mycogen	Resistant to certain insects (expresses Bt toxin)
Bt11	YieldGard†	Corn	Syngenta	Resistant to certain insects (expresses Bt toxin)
CBH-351	StarLink	Corn	Bayer	Resistant to certain insects (expresses Bt toxin)
DBT418	BtXtra	Corn	Monsanto	Resistant to certain insects (expresses Bt toxin)
GA21	Roundup Ready	Corn	Monsanto	Resistant to glyphosate herbicides
GT73	Roundup Ready	Canola	Monsanto	Resistant to glyphosate herbicides
GTS 40-3-2	Roundup Ready	Soybean	Monsanto	Resistant to glyphosate herbicides
MON810	YieldGard†	Corn	Monsanto	Resistant to certain insects (expresses Bt toxin)
NK603	Roundup Ready	Corn	Monsanto	Resistant to glyphosate herbicides

Event	Trade Name	Crop	Company	Trait
T14 and T25	LibertyLink	Corn	Bayer	Resistant to glufosinate herbicides

SOURCE: AGBIOS website (*http://www.agbios.com*), accessed on September 30, 2003.
†Both Syngenta and Monsanto use Monsanto's registered trademark YieldGard for their respective Bt corn events (Bt11 and MON810).

A Generalized Construct Used in Genetic Engineering

Regulatory Sequences	Genes for Traits of Interest	Regulatory Sequences
Promoter	Bt insect resistance or herbicide resistance	Terminator

A Specific Construct Conferring Herbicide Resistance in Soybeans (GTS 40-3-2)

Regulatory Sequences		Genes for Herbicide Resistance Test	Regulatory Sequences
35S promoter from cauliflower mosaic virus	GTP (chloroplast transit peptide) from petunia	EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) gene from *Agrobacterium tumefaciens* CP4	NOS terminator from *Agrobacterium tumefaciens*

SOURCE: AGBIOS database product description, MON-04032-6 (GTS 40-3-2). On the AGBIOS website at *http://www.agbios.com/*

dbase.php?action+showprod&data+gts+40-3-2&frmat=long, accessed on September 30, 2003.

Buying seeds

We bought seeds of all varieties from seed retailers just as growers do. A UCS employee or consultant ordered a bag (approximately 50 pounds) of each variety from seed sellers by phone or in person. The seed sellers shipped the seeds to UCS's Washington, DC, office or a UCS employee or consultant picked up the seeds from the sellers and shipped them by United Parcel Service or delivered them by private vehicle to UCS.

Upon arrival, bags were checked for tears (all arrived with seed bags intact) and were stored in a vacant room within secure UCS offices.

The testing laboratories

To determine whether the seeds contained genetic sequences that might have derived from commercially available engineered varieties, we sent them to two independent, well-established commercial laboratories: GeneScan USA, Inc., and Biogenetic Services, Inc. Both labs specialize in what has come to be called GMO testing—the analysis of food, feed, and other agricultural products to detect sequences from genetically modified organisms (see box, "Basics of plant genetic engineering"). We chose these two companies because of their extensive experience in GMO testing, their scientists' detailed knowledge and expertise, and their excellent performance in the USDA Grain Inspection, Packers and Stockyards Administration proficiency tests.[30]

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[30] For more information on the USDA Grain Inspection, Packers and Stockyards Administration (GIPSA) program, see the

GeneScan USA was established five years ago in Belle Chasse, LA, as a subsidiary of GeneScan Europe, AG, which began GMO testing in 1995.[31] GeneScan Europe has a global network of genetic testing labs in North and South America, Europe, Asia, and Australia. Biogenetic Services is a small, privately owned company founded 15 years ago in Brookings, SD. Despite its small size, Biogenetic Services serves a wide array of customers: government agencies, food and seed companies, elevator operators, insurance companies, law firms, and private individuals.[32]

By submitting samples to two independent companies, we increased our confidence in our overall conclusions. Even so, that confidence is tempered by the recognition that GMO testing is still in its infancy and, unlike older, well-established areas of analysis, has neither standardized protocols and reference materials nor a uniform, worldwide system of laboratory

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USDA GIPSA website at *http://www.usda.gov/gipsa/biotech/proficiency-program.htm.*

31 For more information on GeneScan USA, Inc., see the GeneScan website at *http://www.gmotesting.com.*

32 For more information on Biogenetic Services, Inc., see the Biogenetic Services website at *http://www.biogeneticservices.com.* Also, see examples of Biogenetic Services' clients at: Plant Genome Database—Prototype Developing (at *http://www.nal.usda.gov/pgdic/probe/v1n3_4/maize.html*, accessed on September 23, 2003); Progress in the Development of a Genomic RFLP Map of Cultivated Sunflower (*Helianthus annus*) (at *http://www.intl-pag.org/1/abstracts/101pg1.html*, accessed on September 23, 2003); and Conclusions from a Meeting to Discuss the Interpretation of Test Results on Seed Grown at the Affected Sites in Gisborne and Pukekohe, September 18, 2002 (at *http://www.maf.govt.nz/biosecurity/imports/plants/papers/gm-seeds/appendix-10.htm*, accessed on September 23, 2003).

accreditation.[33] In light of the uncertainties associated with GMO testing methods and the relatively small number of samples for each crop, our primary focus in this study was determining the presence or absence of engineered sequences. While some of the assays did provide information on the levels at which engineered sequences were found in samples, we do not believe the data are sufficiently robust to draw conclusions about the likely levels of contamination in the seed supply.

We conducted two rounds of testing. In Round One, the first laboratory (GeneScan) assayed seed samples of corn, soybeans, and canola to determine the presence of sequences derived from transgenic crops, estimate the levels of contaminants, and run controls for false positives. In Round Two, the second laboratory (Biogenetic Services) tested seeds of the three crops to confirm the first round tests and assayed a duplicate, but larger, sample of seeds to increase the chances of detecting contaminants.[34] Both laboratories

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[33] Anklam, E., P. Heinze, S. Kay, and G. Van den Eede. 2002. Validation studies and proficiency testing. *Journal of AOAC International* 85(3):809-815.

[34] Sample size is a critical factor in the capacity for PCR methods to detect and measure target DNA. Larger samples increase the chances that a given target molecule will be detected and that the amount of the target measured in the sample will be close to the actual amount in the lot from which the sample was taken. For more information on the role of sample size in GMO testing, see Fagan, J. 2004. Detection and Quantification of GMOs by DNA-Based and Protein-Based Methods. Chapter in *Handbook of Food Analysis, second edition*, Marcel Dekker, Inc., in press; Spiegelhalter, F., F.-R. Lauter, and J.M. Russell. 2001. Detection of genetically-modified food products in a commercial laboratory. *Journal of Food Science* 66:634-640; USDA GIPSA. 2000. Sampling for the Detection of Biotech Crops. On the USDA GIPSA

employed widely used testing methods based on polymerase chain reaction (PCR) to detect and identify engineered genetic sequences in the seeds.

Testing method: polymerase chain reaction

Reduced to the simplest terms, PCR testing methods home in on particular target sequences of DNA and, using a special DNA-copying enzyme (DNA polymerase), selectively make enough copies of the target sequence to allow it to be identified and measured. In practice, PCR methods are complicated and require highly trained personnel, sophisticated machinery, and carefully designed tests incorporating many controls and reference standards to ensure accurate and reproducible results.[35]

Designations for regulatory sequences and genes

CTP2/EPSPS CP4	Sequences characteristic of various glyphosate-resistant (Roundup Ready) crops (see the figure, "A Specific Construct Conferring Herbicide Resistance in Soybeans," p. 17)
hmgA	High-mobility group A, a corn-specific gene
le1	Lectin, a soybean-specific gene
nptII	An antibiotic-resistance gene often used as a selective

website at *http://www.usda.gov/gipsa/biotech/sample2.htm*, accessed on November 13, 2001.

35 For more detail on PCR techniques, assay design, controls, reference standards, and interpretation of results, see Fagan, J. 2004 and Spiegelhalter, F. et al. 2001.

	marker in plant engineering
P35S	A promoter from the cauliflower mosaic virus; widely used in transgenic plants
PFMV	A promoter from the figwort mosaic virus
pepC	Phosphoenol pyruvate carboxylase, a canola-specific gene
T-NOS	A terminator sequence (nopaline synthase) widely used in engineered plants

SOURCE: AGBIOS website (*http://www.agbios.com*).

Primers, or primer sets, are a key feature of PCR testing methods; they 'find" the targeted DNA in a mixture of DNA molecules. Primers are short pieces of DNA synthesized to match sequences at the beginning and end of a segment of targeted DNA. When added to a mixture of DNA molecules extracted from a seed sample, the primers bind to the corresponding beginning and ending segments of the target DNA, thereby marking the exact segment to be copied by the DNA polymerase.

The next step, copying the target DNA, involves a series of different reactions, each requiring a different temperature. Thermocyclers subject mixtures of sample DNA, primer sets, DNA polymerase, and other reagents to a carefully controlled regimen of temperature changes—allowing each of the required reactions to proceed under optimal conditions. Each cycle through the temperature regimen doubles the

number of target DNA segments, leading quickly to billions of copies.[36]

Companies use thermocyclers in conjunction with other analytical equipment to generate useful information about the accumulated DNA copies and, by extrapolation, the original sample. GeneScan employed both a qualitative PCR system that determined whether engineered sequences were present or absent in seed samples and a quantitative PCR system to estimate the level of engineered DNA in a sample. Biogenetic Services used a semi-quantitative PCR system that simultaneously detected and estimated the proportion of engineered sequences.

Background on testing strategy

In the study, PCR methods were used for three purposes: to screen for the presence of transgenically derived sequences in the traditional seed samples, to identify the specific transgenic events that were the likely sources of the contaminants, and to estimate the level at which transgenic sequences were present.

Screening for transgenically derived sequences. Screening tests were conducted to determine whether any sequences derived from genetically engineered crops were present in the seed samples. Most of the corn and soybean events currently on the market were engineered with—and therefore likely to contain—either P35S or T-NOS (see box, "Designations for regulatory sequences and genes," p. 19), so primers for those regulatory sequences were used in the initial

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[36] Spiegelhalter, F. et al. 2001. Theoretically, after 32 cycles, a single target molecule would yield just over one billion copies. In actuality, more cycles would be required because each cycle, for various reasons, usually yields less than a doubling.

screen. By probing for those common regulatory sequences, the tests cast a wide net for potential contaminants.

In contrast to corn and soybean events, not all canola events contain P35S and/or T-NOS, so additional primer sets were used to canvas for the presence or absence of canola constructs. In addition to P35S and T-NOS, GeneScan used nptII and CTP2/EPSPS CP4, and Biogenetic Services used PFMV.

Identifying specific transgenic events. In samples testing positive for transgenically derived sequences in the screening assays, subsequent tests were undertaken to identify the specific engineered events. Our approach for identifying these events was slightly different in different crops.

In soybeans, only one commercial event was likely to have contaminated traditional seeds: Monsanto's Roundup Ready soybeans. Even though the U.S. government has allowed two other engineered soybean events on the market (Bayer's glufosinate-resistant soybeans and DuPont's altered-oil soybeans), these events are planted on little, if any, acreage and are less likely to contaminate traditional soybeans. In first-round screening assays, we assumed the genetic sequences detected in soybean samples using primers for P35S and T-NOS came from Roundup Ready (event GTS 40-3-2). Quantitative tests conducted in the first round confirmed that assumption.

Canola seeds testing positive for transgenically derived sequences were assayed for the presence of only one engineered canola event—Monsanto's Roundup Ready (event GT73)—even though other events have been commercialized. Neither lab had the

primer sets necessary to assay Bayer's LibertyLink and SeedLink or Monsanto's Laurical.

Primer sets for many Bt corn events are available to laboratories. The corn samples testing positive for transgenically derived sequences were subjected to additional PCR tests to identify which commercial engineered corn events might be the source of the contaminating DNA. The two laboratories in this study used primer sets recognizing specific commercial corn events such as 176, Bt11, and MON810.

The identification of specific events in this study helped confirm that the genetic sequences detected in screening tests did indeed originate in engineered varieties and ruled out "other seeds" (for example, corn seeds in bags of soybean seed) as major sources of false positive results.

Estimating the levels of transgenically derived sequences. GeneScan and Biogenetic Services provided data on the percentage of genomes in the samples that carried transgenically derived sequences (i.e., the number of genomes containing target DNA detected in comparison to the total number of crop genomes detected in a seed sample times 100). For example, a PCR test detecting 2,000 genomes of Roundup Ready varieties and 1,000,000 genomes of soybean DNA in a sample would report 0.2 percent Roundup Ready DNA.[37]

Round One testing

In Round One, GeneScan tested seed samples from each of six varieties of corn, soybeans, and canola. We weighed, packaged, and shipped approximately 2.5

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[37] For more information on quantifying DNA, see Spiegelhalter, F. et al. 2001.

pounds of seeds of each variety, taking special precautions to prevent cross- contamination of varieties.

[Figure 2-1 omitted]

Detecting transgenically derived DNA. The laboratory ground approximately 3,000 seeds[38] of each variety, extracted DNA from a subsample of the ground material, and used qualitative PCR methods to screen DNA samples. As shown in Figure 2-1, Step 2, primer sets for P35S and T-NOS were used to screen corn and soybean samples, and P35S, T-NOS, nptII, and CTP2/EPSPS CP4 were used to screen canola samples (at a detection limit of approximately 0.1 percent[39]).

Determining specific transgenic events. For samples testing positive for transgenically derived sequences, the laboratory used qualitative PCR methods to determine which specific events might be the source of the contaminating DNA. As explained above, positive corn samples were subjected to further PCR testing to distinguish among a number of commercial engineered events (Figure 2-1, Step 3), and we assumed positive soybean extracts were contaminated with DNA from Roundy Ready (event GTS 40-3-2) soybeans. Canola extracts were subjected to PCR using a primer set for one canola event: GT73 (Roundup Ready).

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[38] The company weighed the equivalent of approximately 3,000 seeds, based on data on weights of aliquots of known numbers of seeds.

[39] A 0.1 percent detection limit means that the methods could not reliably detect target DNA if it were present in the samples at less than a 0.1 percent level.

Estimating the levels of transgenically derived sequences. After determining the presence or absence of regulatory and gene sequences, the laboratory used quantitative PCR methods to estimate the percentage of genomes that carried transgenically derived sequences in positive seed samples (typically at an approximate quantification limit of 0.05 percent[40]). Figure 2-1, Step 4 (p. 21) shows the primer sets used in each crop.

[Figure 2-2 omitted]

Reducing false positive results. Genetically engineered varieties of crops other than the one being tested are potential sources of false positive results. For example, a false positive result in soybean seeds might be the result of contamination with engineered corn seed. We attempted to eliminate this possibility by visually inspecting the samples for seeds of other crops before shipping. Nonetheless, contaminating seeds or pieces of seed remained a possibility.

To determine whether the seed samples were contaminated by engineered sequences derived from other crops, the laboratory assayed positive samples for the presence of DNA from two other crops for which transgenic varieties have been allowed on the market. Using primers for genes unique to each crop, corn samples were tested for the presence of canola and soybean DNA, soybean for corn and canola DNA, and canola for corn and soybean DNA. (See Figure 2-1, Step 5, p. 21, for primer sets used to detect crop-specific DNA.)

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[40] A 0.05 percent quantification limit means that the methods could not reliably measure target DNA if it were present in the samples at less than a 0.05 percent level.

In addition, naturally occurring plant viruses in canola seeds may yield positive results for P35S. The laboratory avoided this potential outcome by using primers for sequences in addition to P35S when testing canola (Figure 2-1, Step 2, p. 21).

Round Two testing

Biogenetic Services tested additional and larger samples of corn, soybean, and canola seeds taken from the same 50-pound bags used in the first round of tests. These second-round tests were undertaken to confirm GeneScan's results and to determine whether larger samples of seeds would increase the likelihood of obtaining a positive result from any one 50-pound bag, thus providing a more accurate picture of the extent of contamination.

Table 2-2 Round One Results: Presence and Levels of Transgenically Derived DNA

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
Corn	1	No	None	None
	2	No	None	None
	3	Yes	MON810 (YieldGard)	Less than 0.05%
	4	No	None	None
	5	Yes	MO810 (YieldGard)	0.1%
	6	Yes	176 (KnockOut/ NaturGard)	Less than 0.2%
			MON810 (YieldGard)	Less than 0.05%
Soybean	7	No	None	None
	8	No	None	None
	9	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0.05%

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
	10	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0,05%
	11	Yes	GTS 40-3-2 (Roundup Ready)	Less than 0.05%
	12	No	None	None
Canola	13	Yes	GT73 (Roundup Ready)	Less than 0.05%
	14	Yes	GT73 (Roundup Ready)	0.05%
	15	Yes	GT73 (Roundup Ready)	0.05%
	16	Yes	GT73 (Roundup Ready)	0.1%

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
	17	Yes	GT73 (Roundup Ready)	0.1%
	18	Yes	GT73 (Roundup Ready)	Less than 0.05%

*See Table 2-1, p. 15.

**Limit of quantification 0.05% except for event 176 (0.2%).

We weighed, packaged, and shipped approximately nine, seven, and three pounds of seeds of each variety of corn, soybeans, and canola, respectively, to the second laboratory using the same protocol, except for sample size, as with the first laboratory. We shipped enough seeds to grind 10,000 seeds of each variety (compared with the 3,000 seeds ground by the first laboratory). The seeds of each variety sent to the second laboratory were scooped from the same bag sampled for first-round testing.

Detecting and estimating the levels of transgenically derived sequences. Biogenetic Services ground approximately 10,000 seeds[41] of each variety of corn and soybeans and extracted DNA from a subsample of the ground material. Using semi-quantitative PCR methods, the laboratory screened DNA samples with primer sets for the common regulatory sequences P35S and T-NOS and estimated the levels of transgenically derived sequences in positive samples (at detection and quantification limits of approximately 0.1 percent). The same process was followed for canola seeds, except the laboratory screened with primer sets for PFMV and did not estimate the levels of transgenically derived sequences (Figure 2-2, Steps 1 and 2).

Determining specific transgenic events. To determine which specific events might be responsible for the contamination, positive samples of corn, soybean, and canola seeds were subjected to additional semi-quantitative PCR tests (Figure 2-2, Step 3, p. 22).

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41 The company weighed the equivalent of approximately 10,000 seeds, bared on data on weights of aliquots of known numbers of seeds.

This time, primers for specific engineered events were used (at a detection limit of approximately 0.1 percent).

Table 2-3 **Round Two Results: Presence and Levels of Transgenically Derived DNA**

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
Corn	1	Yes	Bt11 (YieldGard) MON810 (YieldGard)	Between 0.5 and 1.0%
	2	Yes	176 (KnockOut/NaturGard) MON810 (YieldGard) T25 (LibertyLink)	Approximately 1.0%
	3	Yes	176 (KnockOut/NaturGard) Btll (YieldGard) MON810 (YieldGard)	Approximately 1.0%
	4	No	None	None
	5	Yes	176 (KnockOut/NaturGard) Btll (YieldGard) MON810 (YieldGard)	Approximately 1.0%
	6	Yes	176 (KnockOut/NaturGard) MON810 (YieldGard)	Approximately 1.0%

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
Soybean	7	Yes	GTS 40-3-2 (Roundup Ready)	Between 0.5 and 1.0%
	8	No	None	None
	9	Yes	GTS 40-3.2 {Roundup Ready)	More than 1.0%
	10	Yes	GTS 40-3-2 (Roundup Ready)	More than 1.0%
	11	Yes	GTS 40-3-2 (Roundup Ready)	More than 1.0%
	12	Yes	GTS 40-3-2 (Roundup Ready)	Between 0.1 and 0.5%
Canola	13	Yes	GT73 (Roundup Ready)	QND***
	14	Yes	GT73 (Roundup Ready)	QND
	15	Yes	GT73 (Roundup Ready)	QND
	16	Yes	GT73 (Roundup Ready)	QND
	17	Yes	0173 (Roundup Ready)	QND

Crop	Variety Designation*	Transgenically Derived DNA Detected	Transgenic Events Detected	% of Total Genomes Containing Transgenically Derived DNA**
	18	No	None	QND

*See Table 2-1, p. 15.

**Limit of quantification = 0.1%. Estimates were made of the total transgenically derived DNA detected using P35S and T-NOS, not of individual events.

***Quantification not done.

RESULTS

Overall, the pilot study showed that seeds of traditional varieties of corn, soybeans, and canola are contaminated at a high incidence with low levels of genetic sequences derived from transgenic crop varieties.

Incidence of contamination

Round One results. Transgenically derived sequences were detected in seeds of three of six traditional varieties (50 percent) of corn and soybeans and in all six traditional varieties (100 percent) of canola (Table 2-2, p. 23). Monsanto events were detected in all three crops: MON810 (YieldGard) in the three contaminated corn varieties, GTS 40-3-2 (Roundup Ready) in the three contaminated soybean varieties, and GT73 (Roundup Ready) in all six contaminated canola varieties. Syngenta's event 176 (KnockOut/NaturGard) was detected in one contaminated corn variety.

Round Two results. Transgenically derived sequences were detected in seeds of five of six traditional varieties (83 percent) of all three crops (Table 2-3). Of the five contaminated corn varieties, three contained three transgenic events and two contained two events. Monsanto events were detected in all three crops: MON810 (YieldGard) in the five contaminated corn varieties, GTS 40-3-2 (Roundup Ready) in the five contaminated soybean varieties, and GT73 (Roundup Ready) in the five contaminated canola varieties. Syngenta events 176 (KnockOut/NaturGard) and Bt11 (YieldGard) were detected in four and three contaminated corn varieties, respectively. Bayer event T25 (LibertyLink) was detected in one corn variety.

Table 2-4 **Combined Results of Rounds One and Two: Presence and Levels of Transgenically Derived DNA***

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
Corn	1	No	Yes	None	Btil (YieldGard) MON810 (YieldGard)	None	Between 0.5 and 1.0%
	2	No	Yes	None	176 (KnockOut/ NaturGard) MON810 (YieldGard) T25 (LibertyLink)	None	Approximately 1.0%

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
	3	Yes	Yes	MON810 (YieldGard)	176 (KnockOut/ NaturGard) Bt11 (YieldGard) MONS10 (YieldGard)	Less than 0.05%	Approximately 1.0%
	4	No	No	None	None	None	None
	5	Yes	Yes	MON810 (YieldGard)	176 (KnockOut/ NaturGard) Bt11 (YieldGard) MON810 (YieldGard)	0.1%	Approximately 1.0%

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
	6	Yes	Yes	176 (KnockOut/ NaturGard) MON810 (YieldGard)	176 (KnockOut/ NaturGard) MON810 (YieldGard)	Less than 0.2%*** Less than 0.05%	Approximately 1.0%
Soybean	7	No	Yes	None	GTS 40-3-2 (Roundup Ready)	None	Between 0.5 and 1.0%
	8	No	No	None	None	Nona	None
	9	Yes	Yes	GTS 40.3-2	GTS 40-3-2	Less	More

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
				(Roundup Ready)	(Roundup Ready)	than 0.05%	than 1.0%
	10	Yes	Yes	GTS 40.3-2 (Roundup Ready)	GTS 40-3-2 (Roundup Ready)	Less than 0.05%	More than 1.0%
	11	Yes	Yes	GTS 40-3-2 (Roundup Ready)	GTS 40-3-2 (Roundup Ready)	Less than 0.05%	More than 1.0%
	12	No	Yes	None	GTS 40-3-2 (Roundup Ready)	None	Between 0.1 and 0.5%

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
Canola	13	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	Less than 0.05%	QND
	14	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.05%	QND
	15	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.05%	QND
	16	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.1%	QND

Crop	Variety Designation**	Transgenically Derived DNA Detected		Transgenic Events Detected		% of Total Genomes Containing Transgenically Derived DNA**	
		Round 1	Round 2	Round 1	Round 2	Round 1***	Round 2****
	17	Yes	Yes	GT73 (Roundup Ready)	GT73 (Roundup Ready)	0.1%	QND
	18	Yes	No	GT73 (Roundup Ready)	None	Less than 0.05%	QND

*3,000 and 10,000 seeds of each variety were tested in Round One and Round Two, respectively.

**See Table 2-1, p, 15.

***Limit of quantification = 0.05% except for event 176 (0.2%).

****Limit of quantification = 0.1%.

*****Quantification not done.

Combined results. The positive results in the first round were largely confirmed and extended by second-round tests (Tables 2-4, p. 25, and 2-5). The second laboratory, which used a larger seed sample (10,000 versus 3,000), found a higher incidence of engineered contaminants in corn and soybeans and a lower incidence in canola. In addition, the second laboratory found a larger number of contaminating events in corn varieties than the first. The most conservative expression of the combined results is that transgenically derived DNA was detected in 50 percent of the corn, 50 percent of the soybeans, and 83 percent of the canola varieties tested.

Estimated levels of contamination

Round One results. In contaminated corn varieties, MON810-derived sequences were estimated at levels ranging from 0.1 percent to less than 0.05 percent of the corn genomes present and event 176 was found in one variety at less than 0.2 percent. In all three contaminated soybean varieties, GTS 40-3-2 was estimated to be less than 0.05 percent of the soybean genomes present. The six canola varieties were contaminated with GT73 at estimated levels ranging from 0.1 percent to less than 0.05 percent of the canola genomes present. All Round One assays had a quantification limit of 0.05 percent except for event 176, for which the limit was 0.2 percent (Table 2-2, p. 23).

Round Two results. The second laboratory estimated the levels of transgenically derived sequences in corn and soybean samples based on the total transgenically derived DNA detected by primers for common regulatory sequences. It did not, however,

quantify individual events in corn as did the first laboratory (Table 2-3, p. 24).

In four of five contaminated corn samples, approximately one percent of the corn genomes present contained transgenically derived sequences, while the fifth sample was slightly less contaminated, at less than one percent but more than 0.5 percent of the corn genomes present. In soybeans, the laboratory determined that more than one percent of the soybean genomes in three varieties contained transgenically derived sequences. The remaining two varieties had lower levels of transgenic genome contamination, ranging between 0.1 and 1 percent. All Round Two assays had a quantification limit of 0.1 percent. The second laboratory did not run quantitative assays for contaminants in canola.

Table 2-5 **Combined Results of Rounds One and Two: Percentage of Tested Varieties Containing Transgenically Derived DNA**

	Number and % of Tested Traditional Varieties Containing Transgenically derived DNA*			
	Round 1 (3,000 seeds)		**Round 2 (10,000 seeds)**	
Crop	**Number**	**%**	**Number**	**%**
Corn	3 of 6	50	5 of 6	83
Soybean	3 of 6	50	5 of 6	83
Canola	6 of 6	100	5 of 6	83

*See text and Table 2-4, p. 25, for more detail.

Combined results. In the samples where transgenically derived DNA was detected, the percentage of total genomes containing transgenically

derived sequences ranged from less than 0.05 percent to approximately one percent in corn, less than 0.05 percent to more than one percent in soybeans, and less than 0.05 to 0.1 percent in canola.

Overall, the estimated levels of transgenically derived sequences in contaminated traditional seeds of the three crops ranged from less than 0.05 percent of the total genomes present in the samples to more than one percent. As discussed above, PCR methodology is still in its infancy and lacks standard protocols and methods. As a result, it is difficult to combine data from different laboratories. While we have presented data from quantitative and semi-quantitative analyses of the seed samples we had tested, we do not believe these data are robust enough to draw conclusions about the levels of contamination in the seed supply.

Table 2-6 **Round One Tests for False Positives**

Crop	Designations of Varieties Testing Positive For Transgenically Derived DNA*	Presence (+)/Absence (-) Of Other-Crop DNA
Corn	3	Soybean - Canola -
	5	Soybean - Canola -
	6	Soybean - Canola -
Soybean	9	Corn - Canola -
	10	Corn + Canola -

Crop	Designations of Varieties Testing Positive For Transgenically Derived DNA*	Presence (+)/Absence (-) Of Other-Crop DNA
	11	Corn + Canola -
Canola	13	Corn - Soybean -
	14	Corn - Soybean -
	15	Corn - Soybean -
	16	Corn - Soybean -
	17	Corn - Soybean +
	18	Corn - Soybean -

*See Table 2-1, p. 15.

We note that the second laboratory, which tested 10,000 rather than 3,000 seeds of each variety, reported higher levels of contamination in corn and soybeans than the first laboratory (Table 2-4, p. 25), but we believe different methods and samples make it impossible to interpret this difference. Even preliminary conclusions on the levels of contamination must await a larger study and the development of a standard testing methodology.

Potential false positive results

Of the 12 varieties testing positive for transgenically derived sequences in the first round,

three contained the DNA of other crops: two soybean varieties were contaminated with corn DNA and one canola variety was contaminated with soybean DNA (Table 2-6). Therefore, it is possible that engineered seeds from other crop varieties could have contributed to the positive test results on incidence.

However, that source of contamination could not have accounted for all the engineered genetic sequences detected in the tests because assays with specific primers provided independent evidence that contamination originated in varieties of the tested crop. In the two soybean varieties contaminated with corn DNA, some of the transgenic sequences may have come from corn. But PCR methods used to estimate the levels of engineered genetic sequences relied on a primer set specific for transgenic soybean (the Roundup Ready soybean event GTS 40-3-2). That primer set would not have recognized any commercial engineered corn events.

Similarly, in the canola variety contaminated with soybean DNA, the quantitative PCR testing in Round One was conducted with a primer set specific for transgenic canola (the Roundup Ready canola event GT73). That primer set does not recognize the Roundup Ready soybean event.

UNDERSTANDING THE RESULTS

Extent of contamination

As Tables 2-4 (p. 25) and 2-5 show, one laboratory found engineered contaminants in half the corn and soybean varieties and all the canola varieties. The second laboratory found five of six, or 83 percent, of the varieties of all three crops were contaminated with engineered sequences. Although the sample size is small, the sampling methodology we used suggests that

the contamination of the traditional seed supply is likely to be pervasive.

The 18 varieties we selected were marketed to farmers in states planting the most corn, soybean, and canola seeds in the United States. Four of the six seed companies from which we purchased seed are among the biggest in the country, controlling a substantial portion of the U.S. traditional seed supply. So it is likely that these 18 varieties represent a substantial portion of the 2002 traditional seed supply for these three crops.[42]

It seems improbable that all or most of the other varieties we did not test were free of transgenic contaminants.

Expression of new traits

Not all the contaminants detected by the PCR methods in this study would lead to the expression of engineered traits in the plants grown from these seeds. In general, only those seeds containing intact constructs (i.e., the full complement of regulatory and gene sequences needed to confer the trait) will produce a plant exhibiting new characteristics.

Transgenic constructs may fragment and/or rearrange once they are within a plant genome,[43]

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42 Companies do not release sales data on individual varieties to the public, so we could not determine which varieties were the most widely planted in 2002.

43 Svitashev, S.K., W.P. Pawlowski, I. Makarevitch, D.W. Plank, and D. Somers. 2002. Complex transgene locus structures implicate multiple mechanisms for plant transgene rearrangement. *The Plant Journal* 32(4):433-445. On the Blackwell-Synergy website at *http://blackwell-synergy.com/links/doi/10.1046/j.1365-313X.2002.01433.x*, accessed on November 6, 2003.

leading in some instances to separation of regulatory and gene sequences. Genes alone would produce new protein only in the unlikely event that they were positioned in the neighborhood of a resident regulatory sequence. Regulatory sequences by themselves would not be able to produce novel functional proteins. On the other hand, if they were located in proximity to resident genes, the transgenically derived regulatory sequences may be able to alter the level of expression of those genes and perhaps confer new traits.

Routes of contamination

It is worth emphasizing that this study provides no information on how or when the commingling that led to the contamination occurred. The genetic sequences detected in this study could have moved into traditional seeds by either physical mixing or outcrossing, which could have occurred last year or several years ago. The lack of information on the mode and timing of commingling makes it difficult to speculate on just how extensive the contamination is or where in the production or handling of seeds intervention could have prevented it.

Nevertheless, the study does provide one insight into the role of physical mixing. We initially assumed gene flow rather than physical mixing was the likely primary cause of contamination and predicted that transgenic sequences would most likely show up in corn and canola—crops with outcrossing rates well above that of the predominantly self-pollinating soybeans. The results, however, show all but one traditional soybean variety contaminated with transgenically derived DNA, suggesting that seed mixing during seed production and handling—at

planting, harvest, processing, storage, or transport—may be able to produce widespread contamination.

Illustration of low levels of contamination

As stated earlier, we are not suggesting this study provides a basis for determining overall levels of contamination. The fact that we detected transgenic sequences in so many samples, however, makes it appropriate to consider what low levels of contaminants in the traditional seed supply might mean in practical terms.

To do that, we converted the percentage of total genomes carrying transgenically derived sequences into a percentage of contaminated seeds and then attempted to visualize contamination in three ways: the number of contaminating seeds and the number of 50-pound bags and large (26-ton) tractor-trailer trucks needed to hold the seeds (Table 2-7; Figure 2-3, p. 30; Figure 2-4, p. 31).

Table 2-7 Illustration of Low Levels of Seed Contamination

	Estimated number of seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:		Estimated number of 50-pound bags required to hold seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:		Estimated number of large tractor-trailer trucks* required to hold seeds of transgenic varieties contaminating seeds of traditional varieties at a level of:	
Crop	**0.1%**	**1%**	**0.1%**	**1%**	**0.1%**	**1%**
Corn**	1.6 billion	16 billion	25,000	250,000	24	240
Soybean ***	4.4 billion	44 billion	32,000	320,000	31	308
Canola ****	270 million	2.7 billion	47	470	Less than 1	Less than 1

*We assumed that a large tractor-trailer truck would have a 26-ton carrying capacity. (Iowa Department of Transportation, 1994. Compare cargo capacity. On the Silos and Smokestacks National Heritage Area website at http://silosandsmokestacks.org/resources/images/scans/comparedot.gif, accessed on February 11, 2003.)

**Based on estimates of the number of traditional corn seeds (1.6 trillion) planted in the United Slates in 2002. See text for more detail.

***Based on estimates of the number of traditional soybean seeds (4.4 trillion) planted in the United States in 2002. See text for more detail.

****Based on estimates of the number of traditional canola seeds (270 billion) planted in North Dakota in 2002. See text for more detail.

For the sake of convenience, we assume that the percentage of genomes translates directly into the percentage of seeds carrying genetically engineered sequences.[44] This study reports percentages of total genomes containing transgenically derived sequences ranging from less than 0.05 percent to more than one percent. For the purposes of this exercise, these numbers translate into a range of less than 0.05 percent to more than one percent of the total seeds carrying transgenic sequences in the samples tested.

These levels may appear low, and may lead some to believe that the quantities of seed they represent are small. But that would be a mistake. To emphasize this point, we have estimated the number of contaminating seeds and the number of 50-pound bags and large tractor-trailer trucks required to hold the seeds that 0.1 and 1 percent levels of contamination would represent of the seeds planted with traditional corn,

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[44] The conversion of percentage genomes into percentage seeds contaminated is not straightforward because of issues like ploidy (the number of genomes per cell) and zygosity (whether genetic elements were contributed by one or both parents), some of which may be taken into account by GMO testing companies' adding particular PCR controls.

soybean, and canola varieties. For our calculations, we used data on the acreage planted with traditional varieties of each crop in 2002.

Illustrating low levels of contaminants in Corn and soybean seeds. Using USDA data on the acreage of traditional crop varieties planted and published information on planting rates (number of seeds per acre), we estimated the number of seeds of traditional varieties of corn and soybeans planted in the United States in 2002 to be roughly 1.6 trillion for corn and 4.4 trillion for soybeans.[45]

We then calculated the number of seeds carrying transgenic sequences that would have been planted in fields of traditional corn and soybean varieties if all traditional seed planted in the United States in 2002

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[45] According to USDA NASS data, 79,054,000 acres were planted with corn (*http://www.usda.gov/nass/aggraphs/cornacm.htm*) and 73,758,000 acres were planted with soybeans (*http://www.usda.gov/nass/ aggraphs/soyacm.htm*) in the United States in 2002 (USDA NASS website accessed on May 15, 2003). Approximately 52 million acres, 66 percent of the total corn acreage, were planted with traditional varieties. Approximately 18 million acres, 25 percent of the total soybean acreage, were planted with traditional varieties in 2002 (USDA NASS website at *http://usda.mannlib.cornell.edu/reports/nassr/field/pcp-bbp/pspl0303.pdf* accessed on August 15, 2003). We calculated estimates of planting rates for corn (30,400 seeds per acre) and soybeans (243,000 seeds per acre) from data in Hoeft, R.G., E.D. Nafziger, R.R. Johnson, and S.R. Aldrich. 2000. *Modern Corn and Soybean Production.* Champaign, IL: MCSP Publications, pp. 90-94. Multiplying the traditional acreage for each crop by the estimated planting rate, we arrived at roughly 1.6 trillion and 4.4 trillion seeds of corn and soybean, respectively, planted in traditional varieties in 2002.

had been contaminated at levels of 0.1 or 1 percent (Table 2-7, p. 29, and Figures 2-3, p. 30, and 2-4, p. 31).

[Figure 2-3 omitted]

[Figure 2-4 omitted]

At the 0.1 percent contamination level, 1.6 billion corn seeds carrying transgenic sequences would have been planted in fields of traditional varieties of corn in 2002. At the same contamination level, 4.4 billion soybean seeds carrying transgenic sequences would have been planted in fields of traditional varieties of soybeans.

According to our estimates, it would take about 25,000 50-pound bags (the standard size bought by farmers) or 24 large tractor-trailer trucks to hold the 1.6 billion contaminating corn seeds and 32,000 50-pound bags or 31 large tractor-trailer trucks to hold the 4.4 billion contaminating soybean seeds.[46]

At one percent contamination, 16 billion contaminating corn seeds (or 250,000 50-pound bags or 240 large tractor-trailer trucks) and 44 billion contaminating soybean seeds (or 320,000 50-pound bags or 308 large tractor-trailer trucks) would have been planted along with seed's of traditional varieties.

Illustrating low levels of contaminants in canola seeds. Since the USDA does not publish national data on acres planted with traditional and engineered canola varieties, but that information was available for North

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46 To calculate the numbers of 50-pound bags and 20-ton tractor-trailer trucks required to hold the corn and soybean seeds, we estimated 1,300 seeds per pound for corn (the National Corn Growers Association website at *http://www.ncga.com/education/main/faq.html/#kernel*) and 2,750 seeds per pound for soybeans (Hoeft, R.G. et al. 2000, p. 93).

Dakota, we limited our estimates of traditional canola seeds planted to that state. Based on North Dakota State University estimates of traditional acreage and published information on canola planting rates, we estimated the number of seeds of traditional canola varieties planted in North Dakota in 2002 to be approximately 270 billion.[47]

We similarly estimated the number of canola seeds carrying transgenic sequences that would have been planted in fields of traditional canola varieties in North Dakota in 2002 at a contamination level of 0.1 or 1 percent. Finally, we estimated the number of 50-pound bags[48] or large tractor-trailer trucks that would be required to hold the contaminating seeds (Table 2-7, p. 29).

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47 Berglund, D.R. 2003. Personal communication, August 15. D.R. Berglund is a professor and extension agronomist at North Dakota State University. Since the USDA does not publish information on the percentage of canola acres planted with engineered and non-engineered varieties in the United States, we relied on data from North Dakota State University (NDSU). (North Dakota accounted for nearly 90 percent of the total U.S. canola acreage in 2002.) According to Dr. Berglund, approximately 400,000 (or 31 percent) of North Dakota's total of 1,300,00 acres of canola were planted with non-engineered varieties in 2002. We calculated an estimated planting rate for canola of 678,000 seeds per acre from data published by University of Minnesota [UM] Extension Service, 1999. Canola Variety Trials. Publication MR-7348-GO. On at the UM Extension Service website at *http://www.extension.umn.edu/distribution/cropsystems/DC7348.html*, accessed on August 5, 2002. Multiplying the traditional acreage by the estimated planting rate, we arrived at roughly 270 billion seeds of traditional canola varieties planted in North Dakota in 2002.

48 We used an estimate of 113,000 seeds per pound for canola (UM Extension Service, 1999).

At a 0.1 percent contamination level, North Dakota farmers would have planted an estimated 270 million canola seeds containing transgenic sequences, or 47 50-pound bags (less than one tractor-trailer truck), in fields of traditional canola varieties. At a one percent contamination level, 2.7 billion contaminating canola seeds, or 470 50-pound bags (less than one tractor-trailer truck), would have been planted. The 270 million and 17 billion canola seeds would weigh approximately 1.2 and 12 tons, respectively.

STUDY LIMITATIONS

This pilot study was limited in three important ways.

First, the study tested for only a subset of the genetic sequences present in engineered varieties of corn, soybeans, and canola. As discussed above, GMO testing laboratories can only test for sequences for which they have primer sets, and can only obtain or synthesize primer sets for certain engineered events (primarily those that have been used commercially).

The two laboratories tested for some of the most common transgenic sequences, such as the cauliflower mosaic virus promoter and genes for popular herbicide- and insect-resistance events. However, as noted above, there are other events and regulatory sequences allowed in corn, soybeans, and canola for which the testing laboratories did not have primers. Beyond that, there are many transgenes that are either still undergoing, or have undergone, field tests for which primers are unavailable. To the extent that our study did not test for all possible engineered contaminants, it underestimates the degree of contamination.

The field testing of transgenic corn, soybeans, and canola represents a potentially major source of contaminants not assessed by this study. Since 1987, the USDA has received more than 5,500 applications and notifications of field trials for these three crops—and has denied few. Appendix B contains a list of transgenes and transgenic traits from USDA records of field tests allowed in corn, soybeans, and canola during the last 16 years.

Many, if not most, of the crop-transgene combinations listed in Appendix B will not be commercialized, but they are nevertheless potential sources of contaminating transgenes. The total acreage devoted to field testing is difficult to estimate because one USDA record for a field trial may include tests of multiple transgenes at multiple locations over several years. Since plot sizes typically range from a tenth of an acre to hundreds of acres, however, overall acreage over the past decade and a half is likely to have involved thousands of acres, Many of these tests have been carried out in areas of the country where seed production occurs. Thus, it is possible that transgenes from field test plots have migrated to nearby seed production fields in the past and are still doing so today.

Second, the study looked at the commercial seed supply for traditional varieties of only three crops. It did not include other crops such as cotton and squash, which have engineered varieties in commercial use for which laboratories might have obtained primers. To the extent that seeds for traditional varieties of the crops beyond the three we tested are also contaminated, the overall problem is underestimated by our study.

Third, the study methods do not rule out false positives, or contaminants from other engineered crops. The two corn and two soybean varieties that tested positive for transgenically derived sequences in Round Two but not Round One were not tested for contamination by other crops. Since common regulatory sequences were used by Biogenetic Services to estimate the levels of contaminating DNA in samples, these tests might have picked up genetic sequences contributed by other engineered crops, thereby potentially overestimating the level of genetic sequences contributed by engineered events of the original crop.

Because we did not test for DNA sequences from all the crops with commercially approved transgenic varieties, including cotton and squash, there remains a small possibility that some contaminants in positive samples may have come from those crops.

SUMMARY

For this study, UCS staff bought seeds of traditional varieties of three major commodity crops—corn, soybeans, and canola—and had them tested for genetic sequences originating in transgenic crops. In 18 varieties (six of each crop), we looked for evidence of both regulatory sequences such as promoters, which control gene expression, and genes, which confer herbicide resistance or insect resistance (Bt), from engineered varieties. We found pervasive, low-level contamination from transgenically derived sequences in the seeds of traditional varieties of all three crops.

Although we expected to detect some contamination, we were surprised to find transgenic sequences in most of the varieties tested. The varieties we tested were selected to represent a substantial

portion of the 2002 seed supply for the traditional varieties of the three crops. That is, the 18 varieties we selected were marketed by major Seed companies to farmers in the two states planting the most acres of corn and soybeans and the one state planting the most canola acres in the United States. Therefore, we tentatively conclude that seed contamination in those three crops is not limited to pockets of the seed supply, but is pervasive.

Although they are preliminary, the results of this study suggest the existence of an easy path for the movement of transgenes into the seed supply—one impeded little by current regulations or the standard confinement procedures in commodity crop seed production.

Chapter 3

IMPLICATIONS

Our pilot study suggests that the commercial seed stocks of non-engineered (traditional) commodity corn, soybean, and canola varieties are pervasively contaminated with low levels of sequences originating in genetically engineered varieties. The genes and genetic sequences we detected came from popular transgenic varieties currently allowed on the market in the United States.

Although the study sheds little light on how the contamination occurred, there is no reason to assume that the traits detected in this study were the only engineered traits moving into the traditional seed supply. We would not be surprised if further examination revealed additional traits contaminating a greater number of crop varieties. Until we know otherwise, it is minimally prudent to assume that any

transgenes or transgenically derived sequences being produced and field tested in the United States could move into the seed supply of corn, soybeans, canola, or any other crops with engineered varieties. The vulnerability of the seed production system to contamination is due primarily to its design and standard operating procedures. Contamination is likely to continue unless that system is changed.

Assuming this report's conclusions are borne out by further study, its implications are broad. Seeds are fundamental to agriculture and the food supply, and continued seed contamination can have a potential impact in a number of arenas. We briefly address nine of these below: pharmaceutical and industrial crops, food safety, the environment, trade, organic food production, intellectual property, the food system, the agriculture of developing countries, and seed repositories. In Chapter 4, we present our conclusions and recommendations.

AREAS OF CONCERN

1. Pharmaceutical and industrial crops

The possibility of seed contamination for food crops heightens concerns about pharmaceutical and industrial crops.

Will drug-producing crops end up contaminating our seed and food supplies? Our results suggest reasons for concern. In the near term, this may be the most important implication of our findings.

Agricultural biotechnology is entering a new age. No longer are researchers concentrating only on inserting genes that result in plants with traits like herbicide and insect resistance that make crops cheaper or easier for farmers to grow. Now they are inserting genes to create plants that produce drugs and

industrial chemicals—in essence turning the crops into biological factories. The developers of the new pharmaceutical-producing "pharm" crops especially promise compelling benefits: new drugs that would otherwise be unavailable, and decreased production costs leading to lower consumer drug prices.[49]

A wide variety of genes has been engineered into plants for pharmaceutical and industrial purposes. For more information, see the box, "What kinds of substances are being engineered into pharm and industrial crops?" Many crops containing these genes have been tested in the open environment. Corn is the crop most widely tested for use as a pharm crop, but other food and feed crops including rice, potatoes, soybeans, tomatoes, and canola are also being used. Appendix B includes a list of transgenes from USDA field test records, among which are a number of Transgenes intended for pharmaceutical use. Many other pharm crop transgenes have been tested but their identities are withheld from the public as confidential business information.

What kinds of substances are being engineered into pharm and industrial crops?

The following is a list (gleaned from public sources including industry websites) of experimental pharmaceutical and industrial substances that have been produced in engineered crops. Many of them are bioactive

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[49] Whether the technology can deliver on these promises remains uncertain. Production costs, for example, are just one factor in consumer drug prices, and drug companies often use patents on popular products to charge high prices unrelated to the costs of production and testing.

and/or toxic. Currently, no drugs produced in genetically engineered plants are on the market.

Pharmaceuticals or drugs: Proteins for healing wounds and treating conditions such as anemia, liver cirrhosis, and cystic fibrosis; anticoagulants; blood substitutes; hormones; and enzymes to treat Fabry's and Gaucher's diseases.

Antibodies: Substances that home in on disease-causing molecules with great specificity. Examples include antibodies to fight cancer and tooth decay.

Vaccines: Substances to be injected or given orally to humans and animals to confer immunity to diseases, including non-Hodgkin's lymphoma, rabies, cholera, piglet diarrhea, and foot-and-mouth disease. So-called "edible" vaccines are fruits and vegetables engineered to contain vaccines that will be delivered by ingestion. Currently being developed to fight diseases such as hepatitis 8, measles, and polio, as well as various types of viral diarrhea, edible vaccines were originally envisioned in whole foods such as tomatoes that can be eaten raw, but dosing and quality control considerations have led most developers to consider at least minimal processing of foods and batch production.

Industrial chemicals: Compounds used in the manufacture of products such as paper, plastics, personal care items, and laundry detergents. Examples are trypsin and laccase.

Research chemicals: Substances used in investigative and diagnostic laboratories. Examples include avidin and beta-glucuronidase.

SOURCES: Pew Initiative on Food and Biotechnology (PIFB). 2001. Harvest on the Horizon: Future Uses of Agricultural Biotechnology. Washington, DC: PIFB, pp. 53-63 and references therein; Union of Concerned Scientists (UCS). 2003. Pharm and Industrial Crops: the Next Wave of Agricultural Biotechnology. Washington, DC: UCS, pp. 3-4 and references therein, on the UCS website at *http://www.ucsusa.org/publication.clm?publication/D=538*, accessed June 19, 2003.

The production of drugs and industrial chemicals in corn and other food crops presents obvious risks.[50] If genes find their way from pharm crops to ordinary corn, they or their products could wind up in drug-laced corn flakes. In addition, crops that unintentionally contain drugs or plastics could also prove harmful to domestic animals that eat contaminated feed; to deer, mice, birds, and other wildlife that feed in pharm crop fields; or to organisms living in the soil.

The prospect of pharmaceutical genes contaminating the seeds we depend on for our food supply is genuinely troubling. If seeds are contaminated with genes for drugs, farmers will unknowingly plant and harvest what could be very dangerous crops. The fact that many pharm crops will be planted on small acreage does not assuage the

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[50] Union of Concerned Scientists (UCS), 2003. Pharm and Industrial Crops: the Next Wave of Agricultural Biotechnology. Washington, DC: UCS, pp. 9-11 and references therein, on the UCS website at *http://www.ucsusa.org/publication.cfm?publicationid=538*, accessed on June 19, 2003.

concern.[51] The StarLink incident described in Chapter 1 involved crops planted on less than 0.5 percent of U.S. corn acreage, yet the product ended up contaminating grain throughout the food system. Also affected were the seed stocks of at least 63 small and medium-sized seed companies—more than one-fifth of those contacted by the USDA in the course of the department's seed buyback.[52] StarLink genes may still contaminate the seed supply.

The likelihood that seeds would become contaminated with genes from pharm crops is difficult to assess. It will depend on how the seed contamination occurs (by physical mixing or outcrossing) and a number of other factors, such as whether fields intended for seed production or seed increase for food and feed crops are located close to areas where pharm crops are grown. More study is needed to understand how often seeds are contaminated and where in the seed production process contamination occurs. At this point, we do not have the

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51 Field trials conducted before commercialization usually start with very small plots (less than 1 acre to 10 acres) but can increase dramatically as products get closer to market. At commercialization, some of these products—therapeutic vaccines and certain research chemicals, for example—will likely require only tens of acres to meet the specific demands of those particular markets. Other products, however, will necessitate much larger plantings, ranging up to hundreds of thousands of acres.

52 U.S. Department Agriculture (USDA). 2001. USDA purchases Cry9C affected corn seed from seed companies. USDA News Release, June 15, on the USDA website at *http://www.seeds.gov/news/releases/2001/06/0101.htm*, accessed on November 14, 2003.

information to be assured that pharmaceutical genes have not already moved into our food system.

Pharm and industrial crops, for the most part, remain in the early phases of development. At this point, we should still be able to control the risks of this technology by imposing a strong new regulatory system. Now that we recognize that seeds could become contaminated with pharm or industrial products during the field testing phase and that these genes could make their way into commercial agricultural production, we need to ensure that the seed supply for food crops is explicitly protected in the development of such regulations.

2. Food safety

The prospect of pervasive seed contamination raises food safety concerns for the future, although the particular genes detected in this study do not set off alarms.

There is no reason to believe that genetic sequences originating in transgenic crops *per se* render food unhealthful. Only if the genes or their products cause problems on ingestion is there a food safety hazard, a determination that needs to be made on a case-by-case basis.

The transgenically derived sequences detected in seeds of traditional varieties in this study include both regulatory sequences (e.g., promoters) and genes conferring the traits of interest from the two most popular kinds of transgenic products on the market today. These varieties have passed through the government oversight system for food safety, although only the Bt crops were formally approved for food use

by a federal agency—the Environmental Protection Agency (EPA).[53]

Within the limits of that system, we have no evidence that these transgenically derived sequences are not safe and we do not believe their detection in this study raises food safety alarms. Given the lack of monitoring systems in the United States, lack of reported incidents is not strong evidence of lack of effect, but food ingredients made from these products have been consumed for several years without the emergence of overt problems connected to their origin via genetic engineering.

We do, however, have reservations about the safety of genetically modified food. Our concerns are related less to known problems with the products currently on the market than the lack of scientific rigor in the system evaluating their safety. We have long stressed the need for a mandatory system that would provide a government-backed finding of safety, and have urged the government to undertake or support new basic research to evaluate the potential hazards of genetically modified food (e.g., in the area of allergenicity).[54] As it stands now, the Food and Drug

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[53] The EPA formally approves crops that are engineered to produce plant-incorporated protectants (PIPs) such as the Bt toxin. The agency does not regulate herbicide-resistant crops as PIPs. The Food and Drug Administration (FDA) does not formally approve genetically engineered crops; it merely encourages developers to engage in a voluntary consultation process after which the agency affirms that it has no questions about a biotechnology company's determination of product safety. (FDA. 1992. Statement of policy: foods derived from new plant varieties. *Federal Register* 57:22984-23005.)

[54] Allergenicity is one of the major challenges in the evaluation of a genetically modified food's safety. Scientists currently

Administration (FDA) has little power to compel companies to submit food safety data and does not carry out independent, scientifically rigorous reviews of new transgenic food products.[55]

A new, stronger system would inspire a higher degree of public confidence in the safety of engineered foods, particularly those products that will be brought to market in the future. The system should be based on more rigorous science and include more tests for unexpected effects, as recommended recently by the Codex Alimentarius Commission, an international body that sets food safety standards under the auspices of the Food and Agriculture Organization and the World Health Organization.[56] The U.S. National Academy of Sciences recently conducted a study on the hazards and

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have only limited ability to predict the allergenicity of a particular protein on the basis of its biophysical characteristics. As a result, the protocols used to screen for allergens on the basis of such characteristics are necessarily imperfect. The StarLink variety of Bt corn was denied approval for food uses because its Bt toxin failed screens for digestibility and heat stability. StarLink raises the question of whether other Bt toxins that passed the screens might nevertheless be allergens. It is difficult to resolve this question without a better understanding of food allergenicity. The failure to identify and remedy such a critical research need is a major flaw in the U.S. system overseeing genetically engineered food.

55 Gurian-Sherman, D. 2003. Holes in the Biotech Safety Net: FDA Policy Does Not Assure the Safety of Genetically Engineered Foods. Washington, DC: Center for Science in the Public Interest (CSPI), on the CSPI website at *http://spinet.org/new/pdf/fda_report_final.pdf*, accessed on February 5, 2003.

56 Haslberger, A.G, 2003. Codex guidelines for GM foods include the analysis of unintended effects. *Nature Biotechnology* 21:739-741 (July).

unintended impact of engineered food on human health, and is preparing a report expected to contain recommendations for improving the food safety assessment process.[57]

While most novel gene products will probably prove safe to consume as food and feed, such products are not inherently safe. For gene products that turn out to be harmful, the general concern in the seed contamination context is that the products will make their way into non-engineered seed varieties and be perpetuated in those crops by successive breeding cycles. The new products might not be readily identified as harmful because they would occur sporadically in products not recognized as genetically engineered.

The degree of concern about potential contaminants of food and feed crops varies with their regulatory status and intended use. Transgenic products that have undergone government scrutiny for use in or as food and feed (e.g., for herbicide and insect resistance) tend to raise the least concern, These products were developed for human and animal consumption and have at least been evaluated at some level and screened for obvious problems.

Transgenic products that have not undergone food safety review but have been and are still being field tested raise more concern. Under the U.S. regulatory system, agencies do not analyze genetically modified crops for food safety until after they have undergone

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[57] National Academy of Sciences (NAS). 2003. Project title: unintended health effects of genetically engineered foods. Project Identification Number: BBXX-K-00-02-A. On the NAS website at *http://www.nationalacademies.org/cp.nsf/projects+_by+_pin/bbxx-k-00-02-a?opendocument*, accessed on December 18, 2003.

years of field testing. This means that transgenic crops are potentially available to contaminate the seed supply long before a decision has been made about their safety. Examples of engineered crops that have been field tested but not evaluated for food safety include rice resistant to fungal diseases and corn with modified oils, starches, and proteins.[58] Although not necessarily harmful, transgenic crop varieties that have not been scrutinized are of greater concern than scrutinized products because they have undergone no screen to remove dangerous transgenes.

Finally, gene products that are not intended for use in food raise the highest level of concern. They are unlikely to be reviewed for food safety at all, and many, such as pharm and industrial crops, are likely to produce bioactive and toxic compounds.

Ad hoc accumulation of several novel genes raises food safety concerns. In seed production systems that allow new genes to move into seeds via cross-pollination, every season offers new opportunities for the introduction of new traits. Single plants could accumulate and propagate several different novel traits over time, especially if they offer selective advantages. For example, in the short time that herbicide-resistant canola has been grown in Canada, genes for resistance to three different herbicides have accumulated in individual canola plants—whose offspring show up as weeds in fields planted with canola and other crops. Two of the resistance traits originated in engineered

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[58] Information Systems for Biotechnology (ISB). 2003. Field Test Releases in the U.S. Blacksburg, VA: Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/cfdocs/fieldtests1.cfm*, accessed on October 14, 2003.

canola varieties and one came from a traditionally bred variety.[59]

Whatever food safety dangers may accompany the presence of single novel genes, combinations of genes raise new concerns. The combinations of traits would not likely have been reviewed by agencies for food safety and may present synergistic or otherwise unpredictable effects. Accumulation (or the natural stacking) of traits is most likely to occur in crops whose seeds are routinely saved and planted. Parental lines of hybrid crops or true-breeding crops such as canola or soybeans fit in this category.

3. The environment

The additional risk posed by a transgene contaminating traditional varieties of a crop is likely to be small where the transgene is already present in widely planted commercial varieties of the same crop. Seed contamination, however, offers new routes by which transgenes might make their way surreptitiously to new environments—with unknown effects.

Just as with food safety, the presence of engineered traits in the supply of traditional seeds is not *necessarily* a problem from an environmental perspective. Nothing about genetic engineering suggests that in and of itself, gene products derived from transgenic crops constitute an environmental threat or that engineered sequences inevitably render non-engineered plants dangerous to the environment.

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[59] Hall, L., K. Topinka, J. Huffman, L. Davis, and A. Good. 2000. Pollen flow between herbicide-resistant *Brassica napus* is the cause of multiple-resistant *B. napus* volunteers. *Weed Science* 48:688.694.

But, again, neither are all such crops inherently safe; some do present environmental risks. The nature and degree of these risks depend on the traits added, the plants to which they are added, and the environment within which the plants are situated. Environmental risks are complex in nature and highly context-dependent.

We address the risk issue here within the framework of our earlier report, *The Ecological Risks of Engineered Crops*.[60] That book organized the risks of genetically engineered crops around the notion of weeds—a generic term for plants unwanted by humans, whether in agricultural or nonagricultural settings. In this context, weeds include not only those plants that compete with crops but also those plants that degrade environments of value to humans. Thus, purple loose-strife that decreases the usability of a pond ecosystem by ducks, duckweed that clogs water channels; and kudzu that kills trees are all weeds.

The main environmental risk of genetically engineered crops is that they would become weeds or transfer traits to wild relatives that would become weeds. Whether crops become or give rise to weeds depends on the genes they carry and, importantly, where they are grown. Crops cannot contribute genes to wild and weedy relatives if none exist nearby.

One question here is what additional risk to the environment is posed by a transgene present as a contaminant in traditional varieties of a crop beyond the risks posed by the growth of commercial varieties containing the transgene already permitted in

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60 Rissler, J. and M. Mellon. 1996. *The Ecological Risks of Engineered Crops*. Cambridge, MA: MIT Press.

commerce. In general, as long as the level of contamination remains low, where the transgenes at issue have been allowed on the market and the varieties containing them are widely adopted, the increased exposure due to the contaminants in the seed supply is unlikely to substantially increase exposure to the transgenes or the overall risk. The increase in the levels of Bt toxin coming from contaminated corn seed, for example, will not add much to the overall pressure on the environment resulting from the stream of Bt toxins already in the environment due to commercial Bt products.[61]

On the other hand, seed contamination offers genes and gene products surreptitious paths to new environments. In most cases, neither seed sellers nor farmers would be aware of the contaminant, which would undermine their ability to effectively manage for environmental risks. The greatest risks would be associated with untested or disallowed genes, but even allowed genes might be a problem.

For example, transgenic salt-tolerant rice might be commercialized under conditions designed to keep the plants from invading coastal wetlands. If the transgenes for salt tolerance were to contaminate the traditional rice seed supply, however, their presence would not be known and no precautions taken. The contaminated rice seeds, finding their way to wetlands, could upset a delicate and important ecosystem. Furthermore, if the traits conferred a selective

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[61] Contamination is also generally unlikely to reduce the performance of the crop. For example, a small amount of seed of a drought-tolerant variety planted along with seed of a non-drought-tolerant variety will not interfere with the field production of the non-tolerant variety.

advantage, this would increase the prevalence of the transgenes in the new system.

It is also possible that plants from the transgenic contaminating seeds could breed with wild plants, transferring new traits into wild populations. The effects of such transfers depend on the traits, the receiving populations, and environmental pressures and stresses. But harmful effects are certainly possible.[62] The possibility that some of the large number of transgenes that have already been field tested in more than 40 food and feed crops may already be moving into wild plant populations is troubling.

In contrast to food and feed safety concerns, the relatively low level of contaminating transgenes found in any particular seed batch is not a limit on the amount of harm these transgenes can do in the environment. Considerations of ecological risk must take into account the ability of favorable environments to select for and increase the proportion of harmful transgenes in plant populations.

Contamination with transgenes from pharm and industrial crops raises environmental issues of special concern. These genes may be the sources of toxins that harm wildlife. In addition, toxin production is a common strategy by which plants protect themselves from predators, and pharm genes may provide selectable advantages in wild plant populations. If such transgenes are transferred from pharm crops to weedy relatives or used in crops that have tendencies to

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62 Ellstrand, N.C., H.C. Prentice, and J.F. Hancock. 2002. Gene Flow and Introgression from Domesticated Plants into Their Wild Relatives. In Horizontal *Gene Transfer*, second edition, ed., M. Syvanen and C.I. Kado, 217-236. London: Academic Press.

become weeds, they may enable crops to become weeds or make existing weeds more resilient and difficult to control.

For example, aprotinin, a cow protein that has human medical uses but is also an insect toxin, has been produced in engineered corn plants.[63] If aprotinin genes were to move from aprotinin-producing pharm crops into weedy relatives, the new genes might make the weeds hardier by enhancing their ability to withstand insect predation. The likelihood of pharm genes establishing themselves in weedy populations is enhanced where the pharm genes confer an advantageous trait such as insect resistance.

Seeds contaminated with Bt insect-resistance transgenes could also undermine the effectiveness of so-called resistance-management refuges. Refuges are non-engineered crops planted in the proximity of engineered Bt crops to slow the evolution of insect pests resistant to the Bt toxin. In theory, refuges work by allowing populations of susceptible pests to survive and mate with the relatively rare resistant pests. If the refuges are contaminated with Bt-producing plants, they would likely kill some susceptible pests, thereby aiding the emergence of Bt-resistant insects. Whether the presence of Bt transgenes in traditional varieties of crops would affect the efficacy of refuges would depend

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[63] Zhong, G. Y., D. Peterson, D.E. Delaney, M. Bailey, D.R. Witcher, J.C. Register III, D. Bond, C. P. Li, L. Marshall, E. Kulisek, D. Ritland, T. Meyer, E.E. Hood, and J.A. Howard. 1999. Commercial production of aprotinin in transgenic maize seeds. *Molecular Breeding* 5:335-356. A joint commercial research venture involving Pioneer Hi-Bred (a major seed company), Prodigene (a pharm crop company), and Eli Lilly (a major pharmaceutical company) has successfully engineered corn to synthesize aprotinin.

on the levels of contamination. Low levels of contamination would be unlikely to have much effect.

In general, seed contamination provides an avenue for release into the environment of genes and gene products that have not been evaluated or allowed in commerce and whose presence is unknown to farmers, regulators, or scientists. These may cause problems that are difficult to identify and remedy.

Finally, just as we noted about food safety, our concerns about the environmental risks of engineered crops are exacerbated by the federal government's weak regulatory oversight, its lack of scientific rigor in risk assessments, and its failure to adequately address unintended consequences. The National Academy of Sciences, in recent reports, has criticized both the USDA and the EPA—the two agencies charged with environmental oversight—for failing to develop strong, rigorous regulatory programs.[64]

4. Trade

Seed contamination exacerbates the difficulty of providing non-engineered products to demanding import customers.

Corn and soybeans are major export crops. The United States produces far more of these crops than its own economy can absorb, so it sells aggressively to the rest of the world. While engineered crops are popular

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64 National Research Council. 2000. *Genetically Modified Pest-Protected Plants: Science and Regulation.* Washington, DC: National Academy Press; National Research Council. 2002. *Environmental Effects of Transgenic Plants: the Scope and Adequacy of Regulation.* Washington, DC: National Academy Press.

among U.S., Argentinean, and Canadian farmers,[65] they are highly controversial in other parts of the world, most importantly among some of our major trading partners such as the European Union, Japan, and South Korea.[66]

Resistance in these and other countries has led to a complex set of serious problems for U.S. exporters,[67] most of which are the result of the United States' failure to supply non-engineered bulk products sufficiently free of transgenically derived sequences. This inability is somewhat surprising, considering that the United States, like any good marketer in a competitive industry, should want to satisfy customer demands and capture market share.

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65 International Service for the Acquisition of Agri-biotech Applications (ISAAA). 2003. Global Status of GM Crops: Global Area of GM Crops in 2002. On the ISAAA website at *http://www.isaaa.org/kc/bin/gstats/briefs/.htm*, accessed on June 17, 2003. The United States planted two-thirds of the global acreage of genetically engineered crops in 2002. Four countries accounted *for* 99 percent of the total: United States (66 percent), Argentina (23 percent), Canada (6 percent), China (4 percent).

66 The causes of this resistance are many and complicated. Some resistance stems from consumer concerns and some from desires to protect markets. In addition, genetic engineering has often been presented as an "our way or the highway" proposition, stirring up resentment in parts of the world concerned about looming U.S. hegemony. Finally, there are legal implications to contamination with products that have not been approved in other countries.

67 For more information on trade implications of genetically engineered contaminants, see Taylor, M.R. and J.S. Tick. 2003. Post Market Oversight of Biotech Foods: Is the System Prepared? Washington, DC: Pew Initiative on Food and Biotechnology, pp. 58-04.

The United States grows substantial quantities of non-engineered and organic products that face no customer resistance anywhere in the world and which, in many cases, even command premium prices. But much of the non-engineered grain and oilseed is contaminated with varying levels of genetic sequences derived from engineered varieties. This would not matter if U.S. export customers tolerated contamination with engineered sequences to the same degree they tolerate contamination with other varieties or even other crops, but that is not the case. Many customers want grain or oilseed free of transgenic sequences, especially genes or gene products that have not been approved in their countries.[68] Meeting this demand has proved a difficult challenge.[69]

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[68] Demetrakakes, P. 2000. Processors are trying to gauge the meaning of the backlash against genetically modified crops. *Food Processing Magazine* (March 1). On the *Food Processing Magazine* website at *http://www.foodprocessing.com/web_first/fp.nsf/articleid/meat-4/8nvb*, accessed on November 14, 2003; McMillan, D. 1999. We must provide what customers want. *Western Producer* (September 2). On the *Western Producer* website at *http://www.producer.com/articles/19990902/market_quotas/op mcmillan.html*, accessed on November 14, 2003. Growers can have similar problems in the domestic U.S. market with demanding customers such as baby food manufacturers, many of which also prefer foods free of transgenically derived sequences.

[69] *The Non-GMO Source*. 2001. Export buyers concerned about US ability to provide non-GMO. Volume 1, Number 3, pp. 1-3 (June). The inability to supply the products customers demand has lost the United States important markets, most notably in the European Union, but also in Japan.

Most of the contamination of bulk grain and oilseed products is the result of physical mixing that occurs routinely within the infrastructure of trucks, ships, and grain elevators that moves commodity crops to market. In addition, the outcrossing of pollen from engineered plants into neighboring fields is unavoidable. The existing commodity infrastructure was never intended to transport different segregated streams of grain and oilseed from farms to food and feed processors. As long as the United States grows substantial acreages of engineered crops and does not alter its commodity infrastructure, it will not be able to readily provide uncontaminated commodity grain or oilseed product.

Seed contamination exacerbates the difficulty of keeping engineered genetic sequences out of non-engineered grain and oilseed. Even if growers seeking to export highly pure non-engineered commodity crops could start with pure seed, unreviewed or unwanted transgenic sequences could move into their products via mixing or outcrossing. But, when farmers start with contaminated seed, even the most innovative systems for moving segregated products to market are doomed. Such systems represent new market opportunities and are currently the focus of substantial investments.

It should also be noted that customer preferences are moving targets. If international customers grow more accepting of engineered grain and oilseed, the intermixing inevitable within the current commodity system would cause fewer problems for U.S. exports, and the importance of seed contamination as a contributor to trade problems would be diminished.

Global resistance to genetic engineering, on the other hand, could continue to stiffen and perhaps reach

a point where the United States would have to retool parts of its commodity grain and oilseed infrastructure to enable the segregation of uncontaminated non-engineered products. As discussed earlier, the trend in U.S. agriculture is toward identity-preserved systems.[70] In this scenario, the value of pure non-engineered seed to U.S. exports would increase.

5. Organic food production

The contamination of traditional seed supplies undermines the future of organic agriculture.

Food products that bear the federal organic seal and label have met the U.S. government's standards for the growing and handling of organic food. The core organic standards restrict the use of synthetic pesticides and prohibit the use of irradiation, municipal sludge, and engineered seeds and other engineered inputs in food production. The combination of comprehensive and stringent standards and management systems that enable farmers to meet these standards comprises a holistic approach to food production that works in concert with the environment.

Food that meets organic standards generally commands a premium price in the marketplace. In fact, organic food has sufficient appeal that it is one of the few sectors of U.S. agriculture that is maintaining long-term, double-digit annual growth rates.[71] U.S.

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[70] Strayer, D. 2002. *Identity-Preserved Systems: A Reference Handbook*. Boca Raton, FL: CRC Press.

[71] Dimitri, C. and C. Greene. 2002. Recent Growth Patterns in the U.S. Organic Foods Market. USDA Economic Research Service (ERS), Market and Trade Economics Division and Resource Economics Division, Agriculture Information Bulletin Number 777 (September). On the USDA ERS

certified organic cropland and pasture more than doubled between 1992 and 2001, from fewer than one million acres in 1992 to 2.3 million acres in 2001.[72] Because the organic market offers a value-added product especially important for small and medium-sized farms, the potential loss of this market is of growing importance to U.S. agriculture.

Many organic buyers, processors, and consumers, like many U.S. export customers, are demanding a product free of transgenically derived sequences.[73] To the extent that U.S. organic farmers cannot meet that demand, consumers will go elsewhere or perhaps refuse to pay premium prices. The U.S. government, which touts its organic label as the equivalent of a label indicating the absence of genetically engineered

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website at *http://www.ers.usda.gov/publications/aib777/aib777.pdf*, accessed on December 15, 2003.

72 Dimitri, C. and C. Greene. 2002; Greene, C. and C. Dimitri. 2003. Organic agriculture: gaining ground. *Amber Waves: the Economics of Food, Farming, Natural Resources, and Rural America* (February). On the USDA ERS website at *http://www.ers.usda.gov/amberwaves/feb03/findings/organicagriculture.htm*, accessed on December 15, 2003.

73 Yates, S. 1999. Exported corn chips tainted with GMOs. *Natural Foods Merchandiser* (April). On the New Hope Natural Media website at *http://exchange.healthwell.com/nfm-online/nfm_backs/apr_99/cornchips.cfm*, accessed on May 10, 2003; *The Non-GMO Source*. 2002. Organic farmers report increasing problems with GMO contamination. Volume 2, Number 12, pp. 1-2 (December). Although organic standards do not strictly require a product free of genetic engineering, organic farmers are in a bind because they cannot control the contamination caused by outcrossing originating in their neighbors' fields. They can and have been severely penalized in the marketplace when, through no fault of their own, their harvested products contained traits they did not plant.

sequences, also has an interest in helping organic growers meet the demand.

As discussed above, organic farmers are struggling to find uncontaminated seed. If they cannot purchase seed free of transgenically derived sequences or control post-planting outcrossing—neither of which is completely within their control—they will be unable to meet their own or larger societal demands for non-engineered food. Although it is only one part of the solution, the availability of seed free of engineered substances is essential to meeting consumer demand and preserving an increasingly important sector of U.S. agriculture.

6. Intellectual property

Contamination of non-engineered seeds subjects farmers who have never purchased engineered seeds to the intellectual property laws.

The pervasive contamination of seeds may also have patent implications for farmers who inadvertently plant and harvest seed containing transgenically derived sequences. Under U.S. intellectual property laws, genes, gene products, and engineered crops are now considered patentable subject matter—just like windshield wipers or clocks.[74] Where patents apply, it is illegal for others to make, use, or sell the invention during the term of the patent without permission from the patent holder. To do so could subject the infringer to lawsuits and stiff penalties.

An important feature of the patent law is that infringement does not require intent. Farmers who use genes or seeds patented by others can be sued even if they did not know they were using the invention.

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[74] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

While the law is murky, pervasive seed contamination would appear to put farmers at risk of unknowingly infringing the patents held by biotechnology companies. The threat of patent holders pursuing infringement claims against farmers who inadvertently purchased contaminated seed seems counterintuitive, but it is not impossible. Monsanto, for example, has not been shy about bringing suits against farmers for patent infringement, despite having provoked widespread anger and resentment in rural America.[75]

7. The food system

Seeds contaminated with transgenically derived sequences add a new source of potential food system disruption to the already difficult problems posed by bulk contamination.

The presence of unapproved genes and gene products would of course play havoc with the food system if the traits they confer proved to be harmful, but this could be the case even if they were not harmful. In general, food handlers and processors are not allowed to sell food considered to be adulterated under the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). Food may be considered adulterated for many reasons, including the presence of either pesticidal substances for which the government has not set a tolerance[76] or unapproved food

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75 Monsanto still suing Nelsons, other growers. Cropchoice.com (May 21). On the Cropchoice.com website at *http://www.cropchoice.com/leadstry.asp?recid=826*, accessed on June 23, 2003.

76 21 U.S.C. 342(a)(2), 346.

additives.[77] Products of genetic engineering could fall in either category.

The StarLink episode discussed in Chapter 1 illustrates just how disruptive the presence of an unapproved pesticidal product in the grain and food system can be. The EPA had approved StarLink (a variety of corn engineered to contain a pesticidal Bt toxin) for animal feed but not human food in 1997. The announcement that StarLink corn had been found in taco shells in 2000 set into motion widespread product recalls. Without a tolerance set by the EPA, the presence of the Bt pesticide rendered food adulterated under the FFDCA and therefore illegal.[78] The recalls set off an expensive chain of events as grain sellers and food handlers had to test and divert contaminated lots of grain.[79]

The sources of transgenes that may move into the food supply and trigger similar disruptive events include food crops grown for non-food purposes (for example, corn used as a pharm crop) and engineered crop varieties in the early stages of development prior to commercialization. Transgenes from these sources

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77 21 U.S.C. 342(a)(2), 348.

78 21 U.S.C. 346a(a)(1).

79 The StarLink-related losses for food recalls, lost sales, payments to farmers and grain elevators, and seed buybacks amounted to hundreds of millions of dollars. The USDA ended up bailing out seed companies involved in the effort to contain the contaminants. Demand for U.S. corn abroad plummeted. (Gillis, J. 2003. Little oversight of altered crops. *Washington Post* [April 25]; Howie, M. 2003. Non-StarLink growers reach class action settlement. Feedstuffs [February 24], p. 23; Lambrecht, B. 2001. *Dinner at the New Gene Café*. New York, NY: St. Martin's Press, pp. 51-55; Taylor, M.R. and J.S. Tick. 2003, pp. 90-105.)

might be physically mixed with or outcross into food crops destined for the food system, where they could cause widespread disruption including recalls and lawsuits if discovered.

Seed contamination would exacerbate this problem by making it even more difficult for growers and food companies to know the exact composition of the products they buy and sell.

8. Agriculture of developing countries

Contamination of non-engineered seed in the United States may increase the unpredictability of agriculture in developing countries and may lead to or exacerbate contamination of traditional crop varieties, landraces, and wild progenitors in centers of diversity.

There are two ways that seeds contaminated with engineered sequences could make their way to developing countries: as seeds for planting or as bulk products, which are made up of viable seeds. In developing countries, it is highly likely that seeds purchased as commodity products will be planted by farmers as seeds.

Unsuspecting purchasers of potentially contaminated traditional seed in developing countries will take no precautions to prevent the flow of transgenes into nearby crops and wild and weedy relatives via outcrossing. Since U.S. seeds could be contaminated with many kinds of genes, the consequences of gene movement are difficult to predict. Transgenes that confer fitness benefits on plants can become fixed in plant populations and increase in

frequency in successive generations.[80] Thus, seed contamination could become a conduit for new genes—some of which may be harmful to human health or the environment—into wild and weedy plants.

In general, the most unsettling aspect of seed contamination for producers in the developing world is that there is no way to evaluate, monitor, or avoid such movements because they would occur surreptitiously. Where transgenes move into other varieties or landraces,[81] they could lead to unpleasant—and expensive—surprises. For example, if herbicide-resistance genes move into crop varieties, farmers may find that costly herbicides do not work. Or, if seeds of traditional corn varieties are contaminated with the Bt toxin gene, farmers may find that the crop unexpectedly kills beneficial insects.

The impact of contaminated seed must be considered against the backdrop of genetically engineered varieties that enter a country legally and fully disclosed as a bulk commodity product. It is likely, for example, that Bt transgenes in Bt crop varieties diverted for use as seed would flow through pollen into neighboring crop varieties, landraces, and wild relatives. For popular transgenes such as Bt, the seed diverted from transgenic varieties of commodity crops is likely to be a greater source of novel genes in developing countries than those same transgenes occasionally contaminating seeds of traditional varieties.

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80 Ellstrand, N.C. et al. 2002. Where gene flow is recurrent, even traits with detrimental effects can persist in a plant population.

81 Landraces are plants selected by traditional farmers from wild populations.

The 2001 discovery that landraces of corn in Mexico are contaminated with genetic sequences that originated in engineered corn varieties from the United States underscores the difficulty of confining transgenes used in agriculture.[82] Subsequent studies have confirmed and extended those findings.[83] It is not clear how the genes traveled to Mexico—whether seeds unapproved in Mexico were sold on the black market or bulk products imported from the United States[84] were diverted and used as seed. The Mexican government is attempting to assess the causes and consequences of this finding.[85]

The unexpectedly rapid dispersal of transgenes to Mexico only a few years after their first commercial use in the United States deserves immediate attention from the scientific community because Mexico is the center of diversity[86] for corn, one of the world's most

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82 Quist, D. and I. Chapela. 2001. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. *Nature* 414:541-543 (November 29).

83 Alvarez-Morales, A. 2002. Transgenes in maize landraces in Oaxaca: Official report on the extent and implications. Abstract of presentation at the 7th International Symposium on the Biosafety of Genetically Modified Organisms, Beijing. On the 7th International Symposium website at *http://www.worldbiosafety.net/title9620paper.htm*, accessed on August 14, 2003.

84 Weiner, T. 2002. In corn's cradle, U.S. imports bury family farms. *New York Times* (February 26). Mexico imports about one-fourth of its corn from the United States.

85 Alvarez-Morales, A. 2002.

86 Centers of diversity are regions around the world that harbor populations of free-living relatives of crops. These populations serve as reservoirs of genes that can be moved into crops by traditional breeders.

important food crops. Teosinte, the crop's wild progenitor, can be found growing in Mexican cornfields, and whatever novel genes are found in Mexican landraces are also likely to be transferred into teosinte plants via pollen. While it is impossible with our current level of knowledge to assess the impact of novel genes on teosinte populations, the potential contamination of such important populations of wild plants points to the need for additional research.[87]

The ongoing situation in Mexico highlights the ease with which novel genes and traits can move through agricultural varieties into wild plant populations, including the vital populations that are the centers of diversity for important crops.

9. Seed repositories

If transgenes continue to move into the commercial seed supply of traditional crop varieties, seed repositories may also become pervasively contaminated with a variety of novel genes.

Ongoing contamination of the commercial seed supply could gradually undermine the quality of our communal genetic storehouse for agricultural crops. Nothing is more fundamental to the future of our agriculture and food system than a continued supply of safe, high-quality seed.

The prowess of genetic engineers notwithstanding, seeds cannot be made from scratch. They must be

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87 Sánchez-González, J. 2002. Concerns about the effect of transgene introgression in maize landraces and teosinte. Abstract of presentation at the 7th International Symposium on the Biosafety of Genetically Modified Organisms, Beijing. On the 7th International Symposium website at *http://www.worldbiosafety.net/title9620paper.htm*, accessed on August 14, 2003.

produced generation after generation through highly complex, natural biological processes. The value to food and fiber production embodied in the seeds entrusted to our generation cannot be overstated.

Plant genetic storehouses are maintained through dynamic processes that involve saving, selecting, and storing seeds.[88] A number of groups and institutions are involved in this process. First, as we discussed above, commercial seed companies develop and sell seeds for crop varieties destined for fields or home gardens, in some cases in cooperation with farmers, gardeners, and scientists.[89]

Public-sector plant breeders also develop new varieties, although their role has diminished over the last several decades.[90] Despite the overall decline in university and other public-sector breeding programs, there are new projects under way in land-grant university systems, including the Public Seed Initiative, a joint venture among Cornell University, the USDA, and two organic farming groups.[91]

Farmers also continue to be active in seed selection and preservation. In fact, most of the world's farmers do not have access to commercial seed products and save seeds every season for planting the next season.

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[88] Periodic planting and seed harvesting to replenish stores and increase viability provides opportunities for contamination.

[89] Wheat breeding is a good example of companies, farmers, and university scientists working together

[90] Knight, J. 2003. A dying breed. *Nature* 421:568-570 (February 6).

[91] See the Public Seed Initiative website at *http://www.plbr.cornell.edu/psi.*

In addition to seed stores that are actively managed by companies, scientists, and farmers, some seeds are gathered and kept in repositories called seed banks. Some of the most important seed banks house collections managed by international organizations such as the Consultative Group on International Agricultural Research.[92] These seeds contain genes for valuable traits and combinations of traits that have been selected in a process spanning countless generations. Seed banks are not static collections; the seeds are often removed and planted, and their progeny returned to the seed bank.

Although motley and uneven in its importance to different farmers and gardeners, the sprawling network of seed repositories is vital to the quality and resilience of our food supply. Its importance suggests that we should be highly conservative in our judgment about potential threats to its integrity.

Contamination of seed repositories by transgenically derived sequences is not theoretical. The Charles M. Rick Tomato Genetics Resource Center at the University of California, Davis, recently reported that its seed stock had become contaminated with transgenes originating in a tomato variety engineered to alter processing characteristics. Seed bank officials moved immediately to recall contaminated seed samples that had been sent to

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[92] For more detail, see the Consultative Group on International Agricultural Research website at *http://www.cgiar.org/research/res_genebanks.html*.

researchers in the United States and 14 other countries since 1996.[93]

The magnitude of the threat posed by transgenically derived sequences is not known at this point. As we discussed above, engineered traits *per se* are not necessarily a problem from either an environmental or human health standpoint. Agricultural scientists do not knowingly create harmful varieties (other than, perhaps, for pharm and industrial crops.) Eventually, if engineered varieties are used for a long period without ill effect, seeds from certain engineered varieties will likely be added to seed collections intentionally.

Our experience with transgenic crops to date seems encouraging, but it is limited to a few traits in a few commodity crops. Pharm and industrial crops and other new products[94] dramatically different from Bt and herbicide-resistant products are on the cusp of development, and these engineered crops will exhibit new traits and other features that may warrant a

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93 University of California (UC), Davis. 2003. Tomato seed from seed bank found to be genetically modified. Press release, UC Davis News and Information, December 18, on the UC Davis website at *http://www.news.ucdavis.edu/search/printable_news.lasso?id=6833&table=news*, accessed on December 19, 2003.

94 For a discussion of potential new kinds of engineered crops, see Wolfenberger, L., ed. 2002. Proceedings of a Workshop on Criteria for Field Testing of Plans with Engineered Regulatory, Metabolic and Signaling Pathways, June 3-4, 2002. Blacksburg, VA: Information Systems for Biotechnology (ISB), Virginia Polytechnic Institute and State University. On the ISB website at *http://www.isb.vt.edu/proceedings02/the_proceedings02.pdf*, accessed on August 14, 2003.

higher level of concern than the first generation of transgenic crops.

At this juncture, there remains the remote possibility that the current assurances of safety may be proven wrong—that interfering with natural genetic systems could be setting something seriously amiss. We may be violating rules we do not know exist, passing transgenic sequences into food crops that are in some way generally debilitating, but that we have not yet noticed. Such effects may be accumulating gradually or may need to reach some threshold to manifest themselves.

Until we gain a better understanding of genetic engineering, it is premature to allow transgenically derived DNA and transgenic seeds to creep unobserved into seed repositories.

Chapter 4

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The results of the pilot study presented in this report suggest that seeds of traditional varieties of corn, soybean, and canola sold to growers in the United States contain low levels of genetic sequences that originated in engineered crops. Because we tested seeds of varieties representative of a substantial portion of the 2002 traditional seed supply, we believe that contamination is not an isolated phenomenon but is endemic to the system.

Widespread contamination with genetically modified sequences suggests that production systems for seed sold in the United States are porous—that is,

as currently designed and operated, these systems routinely allow contamination by other crop varieties, including engineered varieties. Unless these standard procedures are tightened, there is little reason to believe that the current level of contamination will decrease. Business-as-usual seed production ensures the perpetuation of contamination and a probable increase in the level and extent of contamination. This is a critical moment for the growers, traders, and food companies who are bearing the managerial costs of testing and segregation, and who will incur liability if incidents similar to StarLink occur again.

In percentage terms, the reported levels of contamination are very low. Nevertheless, as illustrated in Chapter 2, such levels could result in tons of genetically engineered seed being planted each year intermixed with non-engineered seed.

Current concerns: food safety, environment, trade

Today, there is no reason to believe that low-level contamination of non-engineered food crops with genetic sequences from the two kinds of transgenic crops (Bt and herbicide-resistant) detected in the study represents a major threat to human health or the environment. The crops have undergone federal review, and while we agree with the National Academy of Sciences reports indicating that the U.S. regulatory system is not as rigorous as it should be, we do not believe this report justifies raising alarms about the currently unresolved food safety or environmental issues surrounding these crops. Since genetically engineered crops expressing these traits already represent a substantial portion of the grains and oilseeds produced in the United States, the additional presence of contaminants in non-engineered versions of

those crops probably represents a marginal increase in dietary or environmental exposure.

Any assurances about food, feed, and environmental safety, of course, apply only to transgenes that can be detected through testing.

Unfortunately, for practical reasons, many transgenes—including those that have not survived the development process—cannot be detected with PCR-based tests. There are hundreds of such transgenes, some known to the public and some whose identities have been withheld as confidential business information. Field tests of these genetically engineered crops have been conducted for more than a decade in geographic regions where seed production occurs, and the transgenes in these tests represent a potentially large source of contamination.

This study's results should intensify the concerns of consumers who want to avoid genetically engineered foods for ethical, religious, or other reasons. In the United States, where purveyors of food need not disclose the presence of genetically engineered components, such consumers are already deeply frustrated by the lack of information in the marketplace. Contamination of traditional crop varieties with genetically engineered seeds and transgenic sequences only increases the difficulties consumers face.

In the trade arena, the study underscores the point that as long as the United States grows substantial acreages of engineered crop varieties and does not alter its commodity system (including the seed production system), it will not be able to provide uncontaminated commodity grain or oilseed products for any purpose. The lack of this capacity limits the

attractiveness of U.S. products in the international marketplace.

Future concerns: pharm/industrial crops

The most urgent concern arising from this study does not relate to the current generation of products but to future products, in particular pharm and industrial crops. Many of these gene products would obviously be harmful if they were to appear at high levels in food or the environment. If, as the study suggests, the current seed production process is porous to contaminants, it offers a wide conduit through which the genes for pharm and industrial products may find their way into our food and feed systems or environment.

The result of such dangerous substances moving from seeds to consumers could be a disaster for human health. In addition, the economic impact of such an incident would ripple through the U.S. food chain, affecting millers, crushers, and retailers. The possibility that exported grain could be contaminated with substances such as drugs or plastics would further unnerve already wary foreign customers. In short, a contamination crisis similar to StarLink but involving drugs or industrial chemicals could set back, and perhaps even permanently derail, the U.S. agricultural biotechnology industry.

Industry and policy makers interested in pharm and industrial crops should receive this pilot study's message as a wake-up call: The seed supply for major food crops in the United States is vulnerable to contamination with drugs and industrial substances. Until we begin to address the problem of seed contamination, we must assume that pharm and industrial genes introduced into crops could become

low-level contaminants of non-engineered seeds (or even other genetically engineered seeds). As time passes and more transgenes for drugs and industrial chemicals are engineered into plants and tested in the environment, seeds may accumulate higher levels and a greater variety of these foreign genes and sequences.

Time to act

The current government approach to the contamination of bulk grain and oilseed products, landraces, or seeds appears ostrich-like: putting heads in the sand and hoping the phenomenon will go away.

But it will not.

Potential buyers of U.S. export products care about engineered contaminants for a number of legal, cultural, and other reasons and have plenty of other sellers to whom they can turn if the United States cannot meet their demands. From a health and environment standpoint, concerns cannot be written off simply because the levels of transgenically derived sequences are low; novel bioactive substances synthesized in transgenic pharm crops can do damage even at low levels. Moreover, transgenes that escape from the agricultural setting can be propagated in the environment and, in some cases, their levels could increase as a result of natural selection.

The fact—and possible consequences—of contamination can no longer be ignored. These concerns, especially where untested, unapproved substances intended as drugs or industrial chemicals are involved, hang like an ominous cloud over the future of agricultural biotechnology and the global food system.

RECOMMENDATIONS

The contamination of seeds of traditional crop varieties with transgenically derived DNA sequences must be addressed right away. The Union of Concerned Scientists recommends the following actions:

1. **The USDA should sponsor a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by transgenically derived DNA sequences.**

The USDA should follow up this pilot study with a full-scale investigation of the extent, causes, and impacts of contamination of the traditional seed supply by DNA sequences originating in genetically modified organisms. This government-sponsored investigation should include traditional varieties of cotton, corn, canola, soybeans, and wheat, as well as fruits and vegetables for which genetically engineered varieties have been field tested. Although it has not been commercialized, genetically engineered wheat has been extensively field tested without stringent measures in place to guard against seed contamination, The USDA should look for contaminants originating in transgenic crop varieties that are being field tested, as well as in those that have been commercialized.

The investigation should encompass a sufficient number of samples taken from many seed sources in many parts of the country to ensure that its results will be representative of the general state of the traditional seed supply. The sample sizes should be large enough to provide reliable estimates of the extent and levels of contamination.

To address and eventually control contamination of the traditional seed supply by transgenically derived

sequences, it is important to know why and where contamination occurs. There are basically two potential sources of contamination: physical mixing and outcrossing, both of which can occur at a number of points within the seed production process. New research should assess how mixing and outcrossing contribute to seed contamination across the entire spectrum of activities associated with seed production.

Special attention should be paid to understanding the points at which seed production would be vulnerable to contamination by pharm and industrial crops. That will allow scientists to devise strategies to control and prevent contamination in the future (see Recommendation 2).

The needed research is extensive. It must encompass seed production of major commodity crops at corporations, universities, on farms, and among national and international institutions. We recommend that the USDA fund the National Academy of Sciences Standing Committee on Agricultural Biotechnology, Health, and the Environment for the purpose of convening an expert panel to develop the scope and agenda for this research.

2. The USDA, FDA, EPA, and appropriate coordinating elements of the federal government should amend the regulations for transgenic pharm and industrial crops to ensure that the seed supply for food and feed crops is not contaminated at any level with drugs, vaccines, plastics, or related substances.

Protection of U.S. food and feed crops, as well as bulk food products, should be given the highest priority by the federal government in the coming year. We recommend that the USDA, FDA, EPA, and

appropriate coordinating elements of the government amend pharm and industrial crop regulations to ensure that the seed supply for food and feed crops is completely protected against contamination with non-food transgenes and transgene products such as drugs, vaccines, plastics, and related substances.

This is a rigorous standard that is best achieved if pharm and industrial crops are regarded as a drug-manufacturing activity rather than a sideline of commodity crop production. Complete protection of the food supply against pharm and industrial crop contamination may not be achievable if food crops continue to be used as pharm and industrial crops.

Pharm and industrial crops have been planted without adequate control for more than a decade now, and only recently has the federal government awakened to the need for stronger regulation. The USDA recently imposed more rigorous containment procedures on the growing of pharmaceutical and industrial crops, but these new regulations do not even mention, much less address, the issue of seed supply contamination.

The USDA must amend existing pharm and industrial crop rules to deal with this issue and establish new restrictions based on an understanding of the points at which the seed production system is vulnerable to contamination. Such understanding will be the fruit of the additional studies recommended above. In the meantime, we recommend that the USDA immediately require short-term protections for the seed supply, such as

* * *

JA-843

A Growing Concern:
Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops

[Picture omitted]

[Logo omitted] Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

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Chapter 2:
Routes of Contamination

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To evaluate the prospects for preventing contamination of the food supply by pharmaceutical transgenes, we must first identify the routes by which such contamination might occur. The two major routes of contamination (i.e., the presence of pharma transgenes where they are not wanted) are through pollen and seed. Pollen is essential for sexual reproduction and seed formation in corn and soybean. Eliminating the dispersal of pollen is one of the most straightforward ways to prevent biological contamination at a very early stage.

Seeds can be dispersed either naturally, by wind or animals, or by human handling through spillage during seed production, harvest, transportation, and storage. In addition, seeds can be mixed with other seed stocks during these same operations. Seeds spilled during

harvesting, for example, can give rise to plants called volunteers in the next growing season. Grain residues left in a harvester can lead to the mixing of grain from different sources of the same crop.

POLLEN DISPERSAL

Pollen is dispersed mainly by wind and animals. For example, after an insect visits a flower in one population, pollen grains from that flower can stick to its body and be deposited in a flower of a different population.

Pollen dispersal is a natural and widespread phenomenon; at least 12 of the 13 most important food crops in the world cross with wild relatives (Ellstrand 2003; Ellstrand, Prentice, and Hancock 1999). Pollination involving transgenes may move genes for new traits, including pharma traits, from one plant to another.

Unlike synthetic pesticides such as DDT or parathion, which are ultimately degraded in the environment, genes (including transgenes) are replicating molecules. They are able to maintain themselves in living organisms, where they become subject to evolutionary forces such as migration and selection. In some cases, they become extinct in the environment, but in others where, for example, they provide a fitness benefit, their frequency may increase and they may spread in wild plant populations.

Pollen can carry trans genes between crop varieties or between crops and wild or domesticated relatives (Ellstrand, Prentice, and Hancock 1999). This kind of crossing usually leads to viable and fertile offspring that often display more vigorous growth than either parent (Harlan and de Wet 1971). If pharma

transgenes are transferred to and maintain themselves in populations of wild relatives, they could ultimately be reintroduced into non-pharma crops.

Various factors influence the magnitude and geographic extent of pollen movement, including the reproductive mode of the plant, the topography of the surroundings (including the distances among populations), biological and physical characteristics of pollen, environmental factors such as climate and weather, and factors affecting the success of hybridization. Among the latter are the sexual compatibility between parents, presence of compatible plants within pollination distance, sufficient overlap in flowering time, and the actual occurrence of fertilization (Gepts and Papa 2003).

The biological features of corn (*Zea mays*) and soybean (*Glycine max*) differ from one another in ways that affect the likelihood of genes escaping from the crops (Fehr 1980; Russell and Hallauer 1980; Smith 1995). The major difference between the two is that corn is a wind-pollinated plant whose offspring result from unions of pollen and eggs that come from different corn plants (outcrossing), while soybean tends to produce offspring that are the result of unions between pollen and eggs from the same plant (selfing), with only occasional outcrossing involving insect pollinators.

Characteristics of Corn Reproduction

Corn is a species with separate female and male flowers on the same individual plant. The female flowers are found in the ear on the side of the main stem, whereas the male flowers, called anthers, are located in the tassel at the top of the plant.

Each flower in the ear consists of an ovule, style, and stigma. The ovules contain the eggs, which are fertilized by pollen grains. The styles, also called silks, are pollinated when they emerge from the ear's husks. The stigma is the receptive part of the style to which pollen adheres.

An ear has approximately 1,000 ovules. By contrast, anthers in an average tassel will produce approximately 4.3 million to 5.2 million pollen grains (Westgate, Lizaso, and Batchelor 2003). Thus, for each ovule, corn plants produce some 5,000 pollen grains (Kiesselbach 1999). The large number of pollen grains is characteristic of wind-pollinated plants (Cruden 2000).

Two features prevent the release of seeds from a corn ear at maturity as happens in wild corn in Mexico. First, the ear is surrounded by husks, and, second, the ear does not break up to free the seeds.

In corn, male and female flower parts mature at different times to avoid self-pollination. Silks appear one to three days after the anthers on the same plant have started shedding their pollen, and become receptive to pollen when they emerge from the husks. It may take up to five or six days for all silks to emerge from the husks. Each silk may remain receptive for up to 10 days, but high temperature and low humidity decrease this period.

Pollen shedding usually starts three hours after daybreak and continues for one to three hours. Under cooler temperatures and higher humidity, pollen dispersal may be delayed until noon and continue well into the afternoon. Individual pollen grains remain viable for two hours at the most (Luna et al. 2001). The total period of pollen shedding from a tassel can vary

from one to two days to more than a week. So, the actual pollen dispersal time and duration of a given variety are variable and unpredictable because they depend on weather conditions. Whether dispersed pollen will be able to effect pollination depends on the presence of receptive silks, which, as noted above, is dependent on weather conditions.

Corn pollen is dispersed by wind over rather short distances because individual grains are heavy and large compared with pollen grains of other species. The dispersal distance is positively correlated with the size of the source field and wind speed (Raynor, Eugene, and Janet 1972). Other factors that influence pollen movement are gravity, wind direction, turbulence, air density and viscosity, pollen radius, and sedimentation velocity (Di-Giovanni and Kevan 1991; Di-Giovanni, Kevan, and Nasr 1995). Work by Jones and Brooks (1950; cited in Treu and Emberlin 2000) indicates that corn pollen has been observed at 800 meters (0.5 mile) from the source as measured by an outcrossing frequency of 0.2 percent.

Experimental data (Table 2-1) show that pollen concentration 60 meters downwind of the source is equal to one percent of pollen concentration one meter from the source (Raynor, Eugene, and Janet 1972). Luna et al. (2001) observed barely detectable outcrossing at 200 meters (0.1 mile) and none at 300 meters (0.2 mile). Ortiz-Torres (1993; cited in Castillo-González and Goodman 1997) observed 10 to 60 percent cross-pollinated grains in border rows and two to three percent 15 meters from the borders.

In another study, pollen density was higher inside a cornfield at 171 grains per square centimeter (0.15 square inch) and decreased rapidly away from the field

to 14 grains per square centimeter (0.15 square inch) at a distance of two meters (six feet). A single rainfall removed 54 to 86 percent of pollen grains on leaves (Pleasants et al. 2001). *These observations show that long-distance dispersal would be unlikely but not impossible, suggesting that physical isolation or zoning is necessary to prevent the escape of pharma transgenes.*

Table 2-1: Experiments on Pollination Distances in Corn

Sources[a]	Size of source field	Measure	Distance Measured
		Cross-Pollination	
1	—	10-60% 2-3%	1 meter (border) 15 meters
2	45 meters x 45 meters	8-23%	1 meter (border)
3	4,000 meters^2 block	1 event each No event	150 and 200 meters 300 and 400 meters
4	44 meters x 8 meters	Less than 5%	32 meters
		Pollen grains	
5	18 meters diameter	3.8 x 10^6 grains or 1,100 grains/ meter^2	32-60 meters

[a]1. Ortiz-Torres (1993; cited in Castillo-González and Goodman 1997); 2. Murillo-Navarrete (cited in Castillo-González and Goodman 1997); 3. Luna et al. (2001);

4. Chilcutt and Tabashnik (2004); 5. Raynor, Eugene, and Janet (1972).

Characteristics of Soybean Reproduction

Soybean is a predominantly self-pollinating species with very low outcrossing rates. In domesticated soybean, outcrossing rates of only 1 and 0.5 percent have been reported for adjacent plants within rows and between plants of adjacent rows, respectively (Weber and Hanson 1961, cited in Fehr 1980). Ahrent and Caviness (1994) and Nakayama and Yamaguchi (2002) reported a mean of 0.7 percent outcrossing in domesticated soybean, with a range of 0 to 5.89 percent.

Soybean is a highly self-pollinated plant in large part because anthers and stigma are close to each other in the flower. (Unlike corn, single flowers of soybean contain both female and male organs.) The stigma is receptive to pollen one day before flower opening and remains receptive for two days after flower opening. In most flowers, the anthers open and shed their pollen directly on the stigma on the day the flower opens. Under certain circumstances, such as cooler weather, pollen shedding and fertilization take place within closed flowers (Erickson 1975). On average, each of the 10 anthers produces 300 to 800 pollen grains (Palmer, Albertsen, and Heer 1978). Within 10 hours of flower opening, pollen germinates and fertilizes the egg in the ovule (Fehr 1980).

Soybeans may also be cross-pollinated by insects. With nectar consisting of 30 to 50 percent dissolved solids, soybean flowers attract insects (Erickson 1975) such as honeybees, bumblebees, leafcutter bees, Halictid bees, and thrips (Nakayama and Yamaguchi 2002). Genotypic differences in outcrossing among varieties

(Ahrent and Caviness 1994) and higher levels of outcrossing in wild soybean (up to 20 percent according to Fujita et al. 1997; Nakayama and Yamaguchi 2002; Ohara and Shimamoto 2002) suggest a partly genetic control in addition to environmental effects, principally the level of pollinating insects. *Thus, although soybean is predominantly selfing, insect pollination is a mode by which pharma transgenes will escape, if pollinators are present.*

In summary, pharma transgenes may escape via pollen in both corn and soybean, despite their different flower biologies.

SEED DISPERSAL AND MIXING

Seeds can also act as gene dispersal agents in two ways: they can be dispersed naturally—by wind, animals, or humans—or they can be spilled during seed production, harvest, storage, and transportation, which may cause future contamination of crops. These seeds may then grow into plants (volunteers) in future crops or may grow in non-crop areas, which could lead to pollen flow. Other plant parts could be harvested with future crops if not completely covered in tillage operations.

Seed mixing is the inadvertent introduction of unwanted seeds or grains into a seed or grain product during the growing, harvesting, handling, storage, delivery, and processing of that product. In the broadest terms, seed mixing, as applied to grain, is the mixing of two different types (species) of grains, which, in grain industry terms, affects "other crop" purity. An example would be corn grains in a soybean crop sample. A more specific type would be mixing seeds of two different varieties within the same species, which,

in seed industry terms, affects "genetic" purity. An example would be the presence of a small amount of variety B soybeans in a sample of variety A soybeans. In commercial seed, the offending contaminant might not be identified, other than as "off-type."

Seed mixing occurs in both corn and soybean systems and for the same reason: the cropping methods and the equipment used for growing, harvesting, handling, and storage are very similar. The major difference between the two crops is the process of drying the corn grain after harvest. Soybean seeds usually reach storable moisture levels in the field, so there is no need for artificial drying. Corn, however, is harvested in a large part of its production area at moisture levels above those needed for proper storage, and requires drying with air in a grain dryer or in aerated storage bins. Seeds of corn and soybean, stored under dry (less than 10 percent relative humidity) and cool (less than 10°C) conditions, remain viable for several years.

Currently, most of the sampling and testing of the seed mixtures described above involves obtaining a representative sample, making a visual inspection, or conducting more elaborate testing procedures involving enzyme or DNA analyses. Both the grain and seed industries provide tolerances for these types of mixtures. However, these were established to maintain seed purity and are less stringent than a virtually zero contamination standard.

Mixing of pharma crop and food crop seeds may occur at a number of points in seed production and in the grain production/handling/storage system—during the operation of equipment or the transfer of seed or crops between steps in the system. For example, pharma seed may lodge in equipment or facilities and not be

found during the cleaning and inspection between pharma crop and food crop operations. Pharma seed remaining in a combine after harvesting could contaminate the next product harvested with this equipment. At a storage facility, grain spilled during dumping from transportation equipment into storage or processing facilities could become mixed with grain handled later in the same facility.

CONCLUSION

Whether by pollen or seed dispersal or seed mixing, there are many opportunities for the unwanted introduction of pharma genes into non-pharma crops, including food and feed crops. The next chapter will review the options available to block the contamination occurring by these routes.

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JA-855

Can crop transgenes be kept on a leash?

Michelle Marvier[1] and Rene C Van Acker[2]

Debates about the benefits and risks of genetically modified (GM) crops need to acknowledge two realities: (1) the movement of transgenes beyond their intended destinations is a virtual certainty; and (2) it is unlikely that transgenes can be retracted once they have escaped. Transgenes escape via the movement of pollen and seeds, and this movement is facilitated by the growing number of incidents involving human error. Re-examination of our risk management policies and our assumptions about containment is essential as genes coding for pharmaceutical and industrial proteins are being inserted into the second generation of GM food crops. Even the best designed risk management can be foiled by human error, a reality that is underestimated by most GM crop-risk analyses. Thus, our evaluation of risk should assume that whatever transgene is being examined has a good chance of escaping.

Front Ecol Environ 2005; 3(2): 93–100

In a nutshell:

- **The movement of transgenes beyond their intended destinations is a virtual certainty**
- **It is unlikely that transgenes can be retracted once they have escaped**

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- **Human error can foil even the best designed strategies for risk management**
- **Evaluation of risk should assume that transgenes have a good chance of escaping**
- **The second generation of GM plants includes traits which could put humans, as well as ecosystems, at risk following transgene escape**

Genetically modified organisms (GMOs) are now a part of everyday life in the US, with ingredients from GM crops present in the majority of our processed foods (Hopkin 2001). GM crops are also a major feature of our landscape. In 2003, GM crops were grown on 42.8 million hectares within the US alone, an area larger than the entire state of California (James 2003). Genetic engineering promises society everything from crops with improved agronomic and nutritional qualities to frivolities, such as colored lawns and fluorescing pet fish (Figure 1). The possibilities seem to be limited only by our imaginations (Dunwell 1999). Thus far, however, commercially available GMOs have been almost exclusively limited to crops of major economic importance (eg corn, soybean, cotton, and canola), and the commercially introduced traits have been primarily agronomic (eg insect or herbicide resistance; Figure 2).

Different degrees of confinement are warranted for different types of GM crops, depending primarily on the nature of the genetically altered traits and the breeding system of the crops and related species. For those GM varieties that have been deregulated by the US Department of Agriculture (ie approved for widespread commercial production), confinement is

typically not expected. However, there are special cases in which there has been an intent to locally segregate or contain transgenes even for deregulated varieties. For example, some commercially approved GM crops are restricted from being grown in particular states where there are concerns regarding hybridization with weedy relatives; thus, GM cotton can be grown in all states except Florida and Hawaii (EPA 2000). In another well known case, it was assumed that potential risk could be avoided by requiring that seeds remain segregated according to their allowed use; for example, StarLink corn was intended as animal feed but not as human food. The accumulated experiences regarding containment of crops with altered agronomic properties—both before and after their deregulation—provide clear lessons about our ability to contain transgenes.

A second body of evidence regarding containment comes from the last 4 or 5 years of experience with crops that are engineered to cheaply and efficiently produce pharmaceutical and industrial proteins (Giddings *et al.* 2000; see Table 1 for examples of pharmaceutical proteins currently in development). For these varieties there are no realistic expectations of deregulated production—their cultivation will, in all likelihood, forever be limited to "confined" field trials. Examples of the confinement measures for the cultivation of these crops include geographic isolation, scouting for and destroying escaped plants that sprout in subsequent seasons (volunteer plants), and the dedication of equipment for use only on the regulated crop. Inexpensive production of drugs, vaccines, and enzymes would provide benefits to society, but these crops may also represent new risks and they certainly

pose new challenges to our ability to contain transgenes while growing plants outdoors.

The issue of containing transgenes has become a flashpoint in the current debate about biotechnology. If transgenes can be contained, then regulations can be much more permissive about which traits are allowed in crop plants; on the other hand, if transgenes will inevitably escape and spread widely, despite our best intentions (or predictions) of containment, then we need to be much more cautious about what traits are allowed—not only for widespread commercial release, but also in plants that would be grown in small, presumably contained, plots.

Figure 1. *These transgenic GloFish illustrate one end of the spectrum for novelty and frivolity of GM organisms that are currently on the market.*

Twenty years of accumulated experience with biotechnology provides us with a wealth of examples and evidence that bear on the question of transgene

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containment. In this review we provide information to support and emphasize two critical points: (1) the movement of transgenes beyond their intended destinations is a virtual certainty; and (2) it is unlikely that transgenes can be retracted once they have escaped. These points support the need for caution in considerations of the release of GM crops.

Genes move a lot, and often to unintended places

The movement of transgenes follows many different routes. The most obvious one is via pollen, which can be carried long distances by either wind or pollinators (eg Rieger *et al.* 2002; Chilcutt and Tabashnik 2004). Genes can also escape after a crop has been harvested and plowed under because volunteer and feral crop populations can appear in subsequent years and act as potential sources for the reintroduction of transgenes (Gulden *et al.* 2003). Genes also travel great distances when, knowingly or unknowingly, humans transport crop seeds over huge distances, including between continents.

One of the best documented examples of far-ranging gene spread involves canola (*Brassica napus* L). Canola has been genetically engineered to tolerate glyphosate herbicide (Roundup Ready canola) and, separately, to tolerate glufosinate herbicide (Liberty Link canola). With the unconfined commercial release of GM canola in Canada, transgene movement from canola crop to canola crop was predicted (CFIA 1995), but the speed and extent of movement surprised everyone. By 1998, after only two seasons of commercial cultivation of GM herbicide-tolerant canola types in western Canada, volunteer canola plants carrying GM resistance traits were found in many

fields where farmers were not intentionally growing these GM varieties (Hall *et al.* 2000). More importantly, even though the original GM canola possessed either glyphosate tolerance or glufosinate tolerance, individual plants of volunteer canola appeared that possessed both forms of resistance.

Hybridization with other species can be an important additional route for transgene escape. Most crops hybridize with non-crop species in at least some part of their global ranges (Ellstrand *et al.* 1999). Some, such as canola, readily hybridize with related weed species, and we should expect many such hybrids to be created every year. Based on pollen dispersal data, distributions of canola fields, and distributions of weedy mustard populations, Wilkinson *et al.* (2003) estimate that tens of thousands of canola–weed hybrids are produced each year in the UK alone (Figure 3).

Hybridization and gene flow are often controlled by age-old agronomic practices for maintaining seed purity. The most common isolation technique depends on geographic isolation combined with buffers and windbreaks grown around field trials of GM crops (USDA 2003a). Unfortunately, isolation can be broken because pollen flow can cross barriers and surprisingly large distances (Rieger *et al.* 2003; Friesen *et al.* 2003). For example, Reiger *et al.* (2003) studied the movement of canola pollen and detected pollen-mediated gene flow nearly 3 km from a source field. In addition, Watrud *et al.* (2004) found that gene flow from GM creeping bentgrass occurred over 21 km from the source.

Because classical isolation techniques do not provide complete containment, genetic engineers have argued that they can devise technological solutions to

the problem of gene movement. The three most familiar and feasible technical solutions are (1) transformation of chloroplasts rather than nuclear DNA (Daniell *et al.* 1998), because chloroplasts are primarily maternally inherited in most species; (2) the controversial "terminator technology" in which plants are genetically engineered to produce sterile seeds (controversial because this interferes with farmers' ability to save seed), and (3) cytoplasmic male sterility, which involves mitochondrial genes that prevent production of functional pollen. The National Research Council (NRC 2004) recently reviewed these and other bioconfinement tools and concluded that no method is likely to be completely effective. The NRC suggested that rather than relying on bioconfinement, we should put care into selecting host species for certain traits. All GM crops do not warrant the same level of concern. Even among the pharmaceutical crops, there may be certain pharmaceutical proteins that are completely benign to humans and the environment. However, it might be appropriate to restrict plants producing the more high-risk proteins to contained facilities or to disallow their production in food plants entirely (NRC 2004). Clearly, many transgenic proteins will fall in between these two extremes, and the degree of confinement required should depend upon the level of risk to human and environmental health, as well as the risk to public confidence.

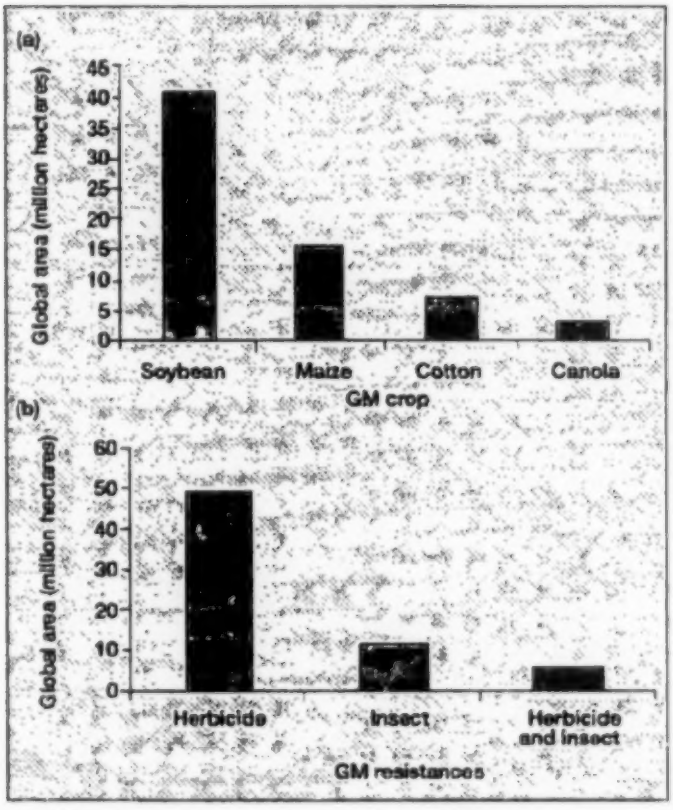

Figure 2. *Global area planted with crops genetically modified for improved agronomic properties in 2003. Areas are shown (a) by crop and (b) by trait. Total worldwide area planted with GM crops in 2003 was 67.7 million hectares. Data are from James (2003).*

Human error and transgene movement

Recent experiences with GM crops suggest that containment will inevitably fail, frequently as a result of human error. Examples include accidental commingling of GM with non-GM seeds or food products, accidental release of unapproved transgenes into commercial seed, and the failure of industry and growers to follow USDA protocols for field trials. Yet risk assessment applied to GM crops has tended to overlook the importance and apparent ubiquity of

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human error and its consequences for transgene escape. A brief summary of a few recent mishaps highlights important issues that should be considered in future risk assessments.

Several major biotech firms were recently fined for violations of safety protocols during field trials of GM crops not yet approved for commercial production. In December 2002, Dow AgroSciences was fined for not establishing proper barriers and windbreaks around a GM cornfield (Gillis 2002a). In that same month, Pioneer Hi-Bred (a subsidiary of DuPont) was fined for growing GM corn in a field that was too near to another corn field, potentially allowing cross-pollination (Gillis 2002a). Pioneer was fined again in March 2003 for failing to report detected contamination among the neighboring corn fields within the allotted time (Gillis 2003a). Similarly, in October 2003, Monsanto was fined for violations that occurred in 2001 field trials of GM corn and cotton (Gillis 2003b).

A disturbing example of human error involved corn genetically modified to produce a vaccine that prevents diarrhea in pigs. In November 2002, the USDA discovered that ProdiGene had failed to comply with federal regulations in two field trials, conducted in Nebraska and Iowa (Gillis 2002b, 2003c). In both locations, ProdiGene failed to destroy volunteer corn plants in the subsequent growing season. In Nebraska, the volunteer corn had been shredded and mixed among soybeans at a grain elevator, necessitating the destruction of 500 000 bushels of soybeans. In Iowa, 155 acres of corn surrounding a test site had to be destroyed because of possible contamination, via pollen, from volunteer plants. ProdiGene was fined $250 000—one of the largest fines ever levied by the

US against a biotech company for a violation of containment regulations.

A particularly puzzling mishap involved transgenes that seem to have escaped industry control and entered the commercial market prior to federal approval (Pollack 2002). In a letter to the USDA (November 9, 2001), Monsanto admitted that small quantities of a non-approved type of GM herbicide-tolerant canola, called GT200, could be present within commercial canola sold in the US. Monsanto requested that the USDA grant retroactive approval of GT200. Although it had never been sold in North America and was not found in commercial canola in the US, GT200 was detected in Canadian canola. Monsanto could not explain how the transgene came to be present in Canadian canola. Aventis CropScience was similarly concerned that some of its GM canola may also have been inadvertently released prior to federal approval.

Seed purity has long been an important issue for agronomists and plant breeders. Recently, Friesen *et al.* (2003) and Downey and Beckie (2002) tested non-GM canola seedlots that were grown in western Canada and found that after only 6–7 years of commercial production of GM canola, the majority of tested seedlots contained at least trace amounts of genetically engineered herbicide-tolerance traits. In fact, 97% (32 of 33) of the seedlots tested by Friesen *et al.* (2003), and 59% (41 of 70) of the seedlots tested by Downey and Beckie (2002) had foreign transgenes present at detectable levels (above 0.01%). The contamination could have resulted from inadvertent mechanical mixing of certified seedlots during harvest or handling, or contamination (possibly from pollen-mediated gene flow) occurring in earlier generations of

pedigreed seed production (ie Breeder or Foundation seed). This high level of contamination in pedigreed seed is noteworthy and disturbing because it shows that even stringent segregation systems were not sufficient to deliver pure non-GM canola seed to farmers in western Canada.

Finally, a probably harmless, yet embarrassing human error was committed by researchers at the University of California (UC). It was recently discovered that the Charles M Rick Tomato Genetics Resource Center at UC Davis had unknowingly distributed seeds of tomatoes containing an approved GM trait to researchers in 14 countries over the past 7 years (Lee and Lau 2003). At least one research project was derailed by receiving this seed. The university has been attempting to recall the approximately 30 seed samples, and has apologized to the recipients.

Although in isolation none of the above examples are terribly alarming, taken together they reveal a worrisome pattern; smart, highly trained, and conscientious people make mistakes, and those mistakes may be repeated and go unnoticed for years. Moreover, although most field trials are performed properly, the rules established to prevent the spread of transgenes from experimental GM varieties are occasionally neglected. The door for transgene escape is occasionally flung wide open. These and similar incidents should serve as a wake-up call to industry, to regulators, and to the public. Transgene movement beyond their intended destination is, for all practical purposes, a foregone conclusion. Unless regulatory oversight and enforcement are improved, containment will fail (Taylor and Tick 2003). As a result, regulatory

policies that assume risk control is possible through containment should be re-examined.

Table 1. Examples of pharmaceutical crops currently in development

Company/institution	*Protein*	*Crop*	*Examples of potential uses*
Meristem Therapeutics	Lipase	Rice	Supplement digestive enzymes in cystic fibrosis patients and others
	Various monoclonal antibodies	Tobacco	Therapeutic proteins to treat cancer and various infectious diseases
	Human serum albumin	Tobacco	Expand blood volume following severe bleeding
	Lactoferrin	Maize	Defense protein that can treat numerous infections
	Collagen	Tobacco	Wound dressings, tissue engineering and artificial skin, wrinkle and scar treatments

Table 1. Examples of pharmaceutical crops currently in development

Company/institution	*Protein*	*Crop*	*Examples of potential uses*
Prodigene	Trypsin	Maize	Protease used in insulin production, cell culture, manufacture of vaccines, and wound care
	Aprotinin	Maize	Protease inhibitor used in cell culture, protein purification, and wound care
Ventria	Lactoferrin	Rice and barley	See above
	Lysozyme	Rice	Small enzyme that attacks the protective cell walls of bacteria; can treat numerous infections
Planet Biotechnology	Antibody to *Streptococcus*	Tobacco	Prevent tooth decay (*Streptococcus mutans* is the

JA-868

Table 1. Examples of pharmaceutical crops currently in development

Company/institution	*Protein*	*Crop*	*Examples of potential uses*
	mutans		bacteria that causes tooth decay)
Chlorogen Inc	Human serum albumin	Tobacco	See above
Iowa State University	E *coli* LT-B subunit protein	Corn	Vaccine against E *coli* infection

This list is not exhaustive but is meant to illustrate the diversity of pharmaceutical proteins that are in development and the variety of crops that are being used to produce them.

No turning back

Unlike most of the agricultural technologies introduced in the past, the decision to introduce transgenic crops on a broad scale may be irreversible. Even persistent pesticides will eventually break down if we simply stop using them, but models from theoretical population genetics suggest that transgenes can persist in the environment for very long time periods. Transgenes that have a selective advantage (eg resistance traits for a herbicide that is used frequently) can easily persist in a gene pool for many generations (Van Acker *et al.* 2003). Even selectively neutral or slightly detrimental genes can persist for long periods, especially if gene flow is ongoing (Ellstrand *et al.* 1999). Although there have been no field experiments that directly assess whether we can remove or recall transgenes once they have escaped into natural gene pools, two lines of evidence suggest that it would be extremely difficult to perform a recall once a transgenic organism becomes widespread. First, although the presence of transgenes will not necessarily make a plant more invasive or harmful, the many failed attempts to eradicate non-native species should alert us to the potential difficulty of eradicating living organisms in general, once they are released or have escaped into the environment. Efforts to eradicate non-native species are often prohibitively expensive and typically involve spraying large quantities of highly toxic compounds that also affect non-target species, including humans (Myers *et al.* 2000). The US, for example, spends about $45 million each year to control a single non-native plant, purple loosestrife (*Lythrum salicaria*; Pimentel *et al.* 2000). Despite these efforts, purple loosestrife continues to

spread rapidly and is now present in 48 states (Pimentel *et al.* 2000).

Second, we need only look to the well known story of StarLink corn to see just how hard it can be to recall a transgene once it has become widespread. Engineered to express insecticidal cry9 protein, StarLink corn was approved for animal feed but not human consumption. It did not, however, remain segregated—in 2000, cry9 was discovered in a wide variety of processed foods. Despite a massive recall of food products and extraordinary efforts to recover StarLink seed, the cry9 transgenes still persisted at detectable levels in US corn supplies 3 years later (USDA 2003b). The lingering presence of StarLink demonstrates that once a transgene makes its way into the general food supply, it may take many years and enormous effort to get rid of it (Figure 4). In contrast to StarLink corn, it is expected that transgenes coding for pharmaceutical and industrial proteins will never become widespread in the first place. However, the StarLink experience shows that should there ever be a massive containment failure, by which an undesirable transgene somehow manages to gain a strong foothold in the seed supply, it may not be possible to subsequently eradicate that gene.

Figure 3. *A field of canola (*Brassica napus *L) in bloom.*

Even with minimal uncertainty regarding the human and environmental safety of GM traits, it would generally be prudent to maintain some non-GM seed lineages for cases where we want to establish cropping systems that are free of GM traits. Unfortunately, recent tests performed on traditional seed varieties of corn, soybeans, and canola in the US, and of canola in Canada, have found pervasive transgenic contamination (Friesen *et al.* 2003; Mellon and Rissler 2004). Although the levels of contamination were generally low (typically less than 1% of individual seeds contain transgenes, although levels of contamination were occasionally much higher), the findings have some unsettling implications for the future. Contamination such as that uncovered by a Union of Concerned Scientists study (Mellon and Rissler 2004) shows just how hard it may be to obtain GM-free seeds in the future.

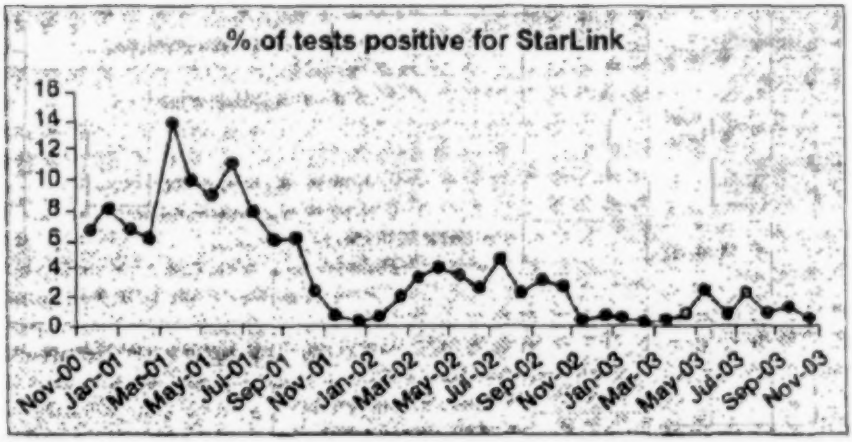

Figure 4. *Persistence of StarLink transgenes in US corn. Because the tests for StarLink are performed on a voluntary basis and not on a statistical sampling of the total US corn crop, the values may not accurately reflect the overall levels of contamination. What is important to note, however, is the lingering presence of StarLink in the samples, despite extensive efforts to recall the transgene. Data from USDA (2003b).*

Does transgene escape matter?

It is not certain whether escape of transgenes, in and of itself, constitutes risk, but escape does enhance the possibility of risk. A particularly well-documented demonstration of possible environmental consequences comes from Snow *et al.* (2003). Commercial sunflowers readily hybridize with weedy sunflowers. Snow and colleagues showed that if a transgene coding for an insecticidal compound moves into weedy sunflowers, the weeds experienced reduced herbivory and produced more seeds. Thus, a problem weed could be made even worse by transgene escape.

Concerning human health, GM foods that are currently on the market do not appear to have caused any great harm, but a recent review by Pryme and

Lembcke (2003) highlights a striking lack of published, independent studies examining effects of GM food and feed on mammals. In contrast to commercialized varieties, there could be serious health consequences if transgenes coding for certain pharmaceutical and industrial proteins were to escape into crops being grown for food or feed—this potential for harm is precisely why the USDA requires strict confinement measures during the cultivation, processing, and transport of these varieties.

Movement of deregulated transgenes into non-GM crop fields can also have important effects on broad agricultural practices. The clearest example of this concerns reduced tillage farming. In reduced tillage cropping systems, non-selective glyphosate herbicide (Roundup) is used instead of tillage to control weeds prior to crop seeding. Reduced tillage provides substantial and measurable economic benefits to farms, in addition to broader environmental benefits (Lafond *et al.* 1992; McRae *et al.* 2000; Derksen *et al.* 2002; Agriculture and Agri-Food Canada 2003; Figure 5). Although the adoption of reduced tillage practices was well underway before GM glyphosate-resistant crops (eg Roundup Ready canola and soy) were first introduced in Canada, the adoption of Roundup Ready crops has facilitated further adoption of reduced tillage practices. Unfortunately, the widespread movement of transgenes conferring glyphosate resistance now threatens the viability of reduced tillage practices. The ubiquitous appearance of Roundup-tolerant volunteer canola in western Canada (Friesen *et al.* 2003) makes glyphosate a selective herbicide; reduced tillage farmers (even those not growing Roundup Ready canola) must now add a second herbicide to the pre-

seeding glyphosate treatment. This adds cost and reduces the economic feasibility of reduced tillage cropping. It also adds herbicide load on the environment (Van Acker *et al.* 2003).

Finally, transgene escape has important implications for those farmers and organizations that are hoping to avoid or minimize the occurrence of GM traits on their land or in their crops and thus, for food processors and consumers who wish to keep certain traits out of food products. If a farmer wants to be certified as organic, or a food provider wants to reassure the public that some food is GM-free, there must be frequent testing and discarding of contaminated seed or grain lots. All this will cost money and create additional costs for entire production systems; currently, where the service is available, genetic purity testing for individual seedlots costs approximately $500.

Figure 5. *With increased soil cultivation (tillage) comes increased risk of erosion—a trend that can be slowed and possibly reversed by the adoption of no-till practices.*

GM crops on the horizon

Although widespread planting of transgenic crops such as herbicide-resistant canola may have environmental consequences, it is typically thought that human health is not at risk. This may change if pharmaceutical and industrial crop production becomes widespread. In 2002, the USDA approved 20 permits for field trials (130 acres on 34 sites) involving plants engineered to produce pharmaceutical proteins (USDA 2003a; see also USDA 2005). A great deal of attention is paid to developing and enforcing confinement protocols for the production of pharmaceutical crops. However, the history of mistakes with previous GM plants suggests that similar mistakes could occur with pharmaceutical crops, where the consequences of lost containment may be more dire. The National Research Council (2004) states that an "organism that is typically grown to produce a common and widespread food product probably would be a poor choice as a precursor for an industrial compound, unless that organism were to be grown under stringent conditions of confinement. Alternative non-food host organisms should be sought for genes that code for transgenic products that need to be kept out of the food supply." However, of the over 200 field trials conducted to date for GM crops producing pharmaceutical or industrial products, over 75% involved corn—a wind-pollinated and out-crossing food crop (UCS 2003). Moreover, even *Nature Biotechnology*, a journal that most would label as pro-biotechnology, challenged the wisdom of using corn for pharmaceutical production. The editorial board of *Nature Biotechnology* (2004) wrote: "It seems that an industry in which the PhD is the intellectual norm is either incapable of learning a simple lesson from the

past or cannot bring itself to act appropriately, despite what it has learned previously". Pharmaceutical crops make the issue of containment and human error a matter of public health as well as an environmental concern.

Conclusions

GM crops are here to stay, and they may produce numerous societal benefits, including inexpensive production of drugs and more nutritious foods. Advocates of biotechnology often point to the precision of the technology and our mastery of DNA as reassuring. Perhaps it is, but we will never be able to master and fully eliminate human error. The inevitability of mistakes, and therefore of transgene escape, must be factored into our policies, regulations, and risk assessments for GM plants. There is therefore a pressing need for the development of models that simulate the entire lifecycle of those transgenic crops that do require confinement—from the time when seeds leave a company's custody until they are planted in a field, harvested, processed, and successfully shipped to a processing facility. These models should include detailed information about all possible routes for transgene escape, including biological processes such as long-distance pollen dispersal, seed movement by animals, and viability of seeds following consumption by animals. Just as importantly, these models must include routes of transgene escape that result from human error, such as a failure to perform appropriate scouting for volunteers, inadvertent mixing of GM and non-GM products, inadequate cleaning of equipment, and violations of procedures for chain of custody. There are many possible points at which containment could be breached, and data are

needed to estimate probabilities at each of these points. These models, if properly parameterized, should help regulators to identify where to build in redundancies to improve confinement, and many of these redundancies will need to be aimed at human error. However, we must keep in mind that even the best designed risk management with redundancy and enforcement can still be foiled by human error. We should not have confidence in our ability to keep GM plants on a tight leash. Rather, total containment can never be assured or assumed, and our evaluation of risk should be predicated on the idea that transgenes always have some chance of escaping. Re-examination of our risk management policies and of our assumptions about containment is essential as we move into the second generation of GM crops, some of which will have the potential for serious adverse effects.

Acknowledgements

M Marvier was supported by a grant from the Biotechnology Risk Assessment Research program of the National Center for Environmental Research of the US EPA.

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GENETICALLY MODIFIED CROPS

Tracing the Transatlantic Spread of GM Rice

Amid product recalls and plummeting prices, scientists are trying to figure out exactly how traces of an experimental variety of genetically modified (GM) rice ended up in commercially available supplies in the United States and Europe. Although the herbicideresistant strain was never approved or marketed, traces of it have appeared in samples collected on both continents. Agriculture officials stress that the rice poses no health threat, but its spread is a cautionary tale that introduced genes may be harder to contain than some scientists and industry leaders had hoped. The finds "set a really bad example for genes that we do want to keep contained," says plant geneticist Norman Ellstrand of the University of California, Riverside.

The variety, called Liberty Link 601 (LL601), was grown in test plots in several states between 1998 and 2001. Designed to be resistant to the broad-spectrum Liberty herbicide sold by Aventis CropScience (later bought by the German company Bayer), it was not as successful as hoped, and Aventis discontinued research on the strain in 2001. In late July, Bayer notified the U.S. Department of Agriculture (USDA) that it had found traces of LL601 in commercial samples of long-grain rice stored in Arkansas and Missouri. When USDA announced the find two and a half weeks later, U.S. rice prices fell by nearly 10% in 2 days.

On 11 September, European Union officials confirmed that 33 of 162 samples tested by rice millers across Europe, a major importer of U.S.–grown rice, had shown traces of LL601. Officials in Sweden and

France also said they found traces of the gene in commercially available rice. And Greenpeace said it had found traces of LL601 in rice for sale at Aldi supermarkets in Germany, prompting a nationwide recall.

How the gene spread so far is still a mystery. Rice is thought to pose a relatively low risk of cross-contamination because it self-pollinates, often before the flower even opens, lowering the likelihood that wind or insects could spread GM pollen. Steve Linscombe, a rice breeder at Louisiana State University (LSU) in Baton Rouge, where some of the test plots were grown, says they strictly followed USDA standards, exceeding the minimum requirements for buffer zones between the test plots and conventional rice. However, the university did say it found "traces of genetic material" from LL601 in samples of foundation seed rice grown at LSU in 2003 for the widely grown Cheniere variety. Foundation seed is the original stock of a commercially available variety. It is distributed to seed-producing farmers, who then plant it to grow seed rice that is sold nationwide. Linscombe says the university is working with USDA to determine how the LL601 gene could have entered the Cheniere seed stocks.

Doug Gurian-Sherman of the Center for Food Safety in Washington, D.C., says regulations designed to limit the spread of introduced genes should require more extensive testing of such seed stocks. The possibility of contamination "needs to be taken seriously," he says. Ellstrand says that a careful investigation of what led to the spread will be crucial for scientists planning field trials of GM plants that

contain more sensitive genes, such as those for pharmaceuticals or industrial products.

- GRETCHEN VOGEL

Fertile questions. Scientists are trying to trace how an experimental strain of genetically modified rice spread to rice sold in the U.S. and Europe.

GENE FLOW FROM TRANSGENIC CREEPING BENTGRASS (*AGROSTIS STOLONIFERA* L.) IN THE WILLAMETTE VALLEY, OREGON

J. K. Wipff and C. Fricker

ABSTRACT

Since the Willamette Valley produces nearly all of the bentgrass (*Agrostis* spp.) seed grown in the United States and exports bentgrass seed in large quantities to Europe, risks associated with the commercial production of transgenic cultivars in the major grass seed production area of the world must be defined. Bentgrass can be a serious weed in other crops. Since creeping bentgrass may be the first perennial, wind pollinated, outcrossing, transgenic grass species to be produced commercially, essential data must be generated on pollen movement within the crop. Pollen flow, viability, pollination and seed formation are all sensitive to climatic parameters, which differ greatly from region to region, so it is imperative that this research be conducted where the crop will be commercially cultivated. The two primary objectives of this study were to investigate intra- and interspecific gene flow of transgenic creeping bentgrass in the Willamette Valley of Oregon. Pollen movement was determined by placing transects of non-transgenic creeping bentgrass around a nursery of 286 transgenic plants genetically engineered for tolerance to the herbicide glufosinate. Approximately 250 non-

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transgenic creeping bentgrass plants were planted in transects around the transgenic nursery in 1998 and 1999 near Hubbard, OR. In 1998, the following transects were established: 1) two circles around the nursery at 109 (33.2 m) and 272.5 ft (83.1 m) with plants spaced at 50 ft (15.24 m) and 100 ft (30.48 m), respectively; and 2) two line transects aligned with prevailing winds (NE) with one transect NE 244 ft (74.4 m) and the SW transect 370 ft (112.8 m) from the edge of the nursery based on Oregon Seed Certification isolation distances, which is 165-300 ft (50.3-91.4 m) (depending upon field size) for certified seed production. In 1999, the length of the line transects were increased to the following: 1) SW transect, 978 ft (298.1 m); 2) NE transect, 268 ft (81.7 m); 3) SE transect, 612 ft (186.5 m); and 5) NW transect, 319 ft (97.2 m). Using nonlinear regression, the following distances were predicted for transgenic pollen introgression to the 0.02% level. In 1998, along the SW transect, transgenic pollen traveled 3,500 ft (1,066.8 m) and along the NE transect it traveled 4,296 ft (1,309.4 m). In 1999, the transgenic pollen was estimated to have traveled 1,022 ft (331.5 m) to the SW, 1,892 ft (576.7 m) to the NE, 861 ft (262.4 m) to the NW, and 1,022 ft (331.5 m) to the SE. The second part of the study was to evaluate interspecific hybridization in creeping bentgrass for its propensity to hybridize freely. Twelve species of bentgrass have been documented as occurring in the area of bentgrass seed production. Six are naturalized species and are part of a complex that freely hybridize: *A. canina* L., *A. capillaris* L., *A. castellana* Boiss. & Reuter, *A. gigantea* Roth, *A. stolonifera*, and *A. vinealis* Schreber. Accessions of *A. canina*, *A. capillaris*, *A. castellana*, *A. curtissii*, *A. gigantea*, *A. pallens*, and *A.*

sp. were placed in the transgenic nursery prior to flowering and allowed to interpollinate. The crossing experiments resulted in the introgression of the bar gene from creeping bentgrass into *A. canina*, *A. capillaris*, *A. castellana*, *A. gigantea*, *A. pallens*, and *A.* sp. These data will be available to USDA-APHIS for use in creating a risk assessment model for commercial transgenic grass seed production.

INTRODUCTION

The importance and value of turfgrass is accelerating, due to its association with an ever-increasing urban population. In the United States alone there are over 14,000 golf courses, 40,000 athletic facilities, and 40 million home lawns and parks [Edminster, 2000]. This importance can also be seen in the size of the turfgrass seed market, which is only second to that of hybrid seed corn [Lee, 1996], with annual sales between $580 million - 1.2 billion. Although turfgrass management and production is one of the fastest growing areas of agriculture, genetic transformation of turfgrasses lags behind that of many other important crop plants [Johnson and Riordan, 1999]. Though conventional plant breeding can incorporate individual and multiple stress tolerance, as well as, agronomic traits, there are biological limits to how far a species can be manipulated by traditional plant breeding methods and progress can be extremely slow, costly, and sometimes impossible. DNA biotechnology can provide new, efficient, and innovative methods for the incorporation of not only individual, but also complex, multiple abiotic and biotic stress tolerances [Dale, 1993; Lee, 1996; Brilman, 1997; Duncan and Carrow, 1999] that would be extremely

difficult, if not impossible using classical plant breeding methods.

DNA biotechnology expands the available gene pool to include every living thing. Primary, secondary, or tertiary gene pools [as defined in Harlan and de Wet, 1971] in traditional plant breeding no longer exist, but anything with DNA is now in the primary gene pool. Transformation technologies allow plant breeders to combine the genes for a trait from different species. In conventional plant breeding, the level of difficulty in developing new cultivars is related not only to the genetics and complexity of the trait(s) of interest, but also to the number of undesirable traits or characteristics in the parents, which is dependent on which gene pool the parent belongs. When a trait(s) is transferred via traditional plant breeding methods it carries a number of undesirable traits which must be removed. The further down the gene pool that a desired trait is located, the more undesirable genes that must also be dealt with. With DNA biotechnology, only the gene(s) of interest are incorporated into the plant genome; thus no time is needed for repeated backcrosses to remove undesirable genes.

DNA biotechnology offers two new types of tools for plant breeders: Genomics and Plant Transformation [Sage, 1999]. Genomics involves the technologies of mapping and selecting genes. This provides a tool for the plant breeder to track the genes controlling comparable traits in different species. Plant transformation involves building genes into constructs that can then be rapidly moved across species. Genomics can be divided into two further divisions: Structural and Functional. Structural Genomics is the process of determining gene location in

a genome and has led to discovery of colinearity or synteny: the conservation of gene order on chromosomes across different species within families. Functional Genomics is the process of finding out what individual genes control at the biochemical level, which leads to the discovery of many new and potentially economically important traits. Microarray analysis provides a way to link genomic sequence information (Structural Genomics) with Functional Genomics [Lemieux et al., 1998]. Future techniques will be based on DNA sequences in the genes themselves, rather than by linked markers [Barker and Warnke, 1998]. Sequence recognition will be done using DNA microarrays and chip technology. DNA chip technology utilizes microscopic array (microarrays) of molecules immobilized on solid surfaces for biochemical analysis. Microarrays can be used for expression analysis, polymorphism detections, DNA resequencing, and genotyping on a genomic scale. Microarray-based characterizations of plant genomes has the potential to revolutionize plant breeding and agricultural biotechnology. Microarrys allow for the rapid analysis of transgenic plants. These data will permit genome-wide correlations between expression patterns and a host of desirable traits such as fertility, seed set, yield, and resistance to abiotic/edaphic and biotic stresses. Costly field trials could be reduced using chip-based analysis of transgenic lines. Micoarrays in gene sequencing and diagnostics will greatly escalate the identification of DNA polymorphisms, which in turn could be used to expedite plant breeding by allowing simultaneous analysis of thousands of polymorphisms in a single experiment. Thus this technology has the potential to be a powerful selection tool that could eventually replace marker assisted selection. DNA

technologies will also be important in the protection of intellectual property rights by serving as the molecular identification tools to distinguish between turfgrass cultivars or to actually insert a patented DNA sequence into a cultivar as an identification tag. Plant breeding will be revolutionized as gene technologies become more efficient and economical.

DNA biotechnological enhancement is being considered for virtually all commercially important plants and the number of field tests for transgenic plants is increasing exponentially. For example in perennial grasses, the following is the number of permits/notifications have been issued or pending (number submitted) by USDA/APHIS (http://www.nbiap.vt.edu/cfdocs/fieldtests.cfm):

Species	1993-1997	1998	1999	2000
Creeping bentgrass	11(12)	16(19)	25(26)	20(24)
Kentucky bluegrass	—	1(2)	8(8)	7(7)
Perennial ryegrass	—	—	1(1)	1(1)
Tall fescue	—	—	2(3)	1(1)
Bermudagrass	—	—	2(2)	2(2)

Many of the applications of DNA engineering in agriculture will probably have neutral or even beneficial environmental consequences, but commercial-scale production of some of these transgenic plants could lead to undesirable environmental and agricultural consequences [Snow and Moran Palma, 1997]. Environmental consequences for the commercialization of transgenic crops [e.g.

Colwell et al., 1985; Rogers and Parkes, 1995; Tiedje et al., 1989] has been debated extensively. On one side, the argument is that the phenotypes of transgenic plants are similar to phenotypes of plants developed through conventional breeding methods and that these plants are therefore not inherently risky [e.g. Brill, 1985; Miller, 1994]. On the other side, the argument is that the access to unlimited numbers of genes from unrelated organisms makes genetic engineering a new and potentially dangerous technique, with the major concern being evolution of undesirable weeds or pesticide resistant insects [e.g. Ellstrand and Hoffman, 1990; Rissler and Mellon, 1993; Tiedje et al., 1989]. These risks and concerns also apply to traditionally bred crops as well, but the release of transgenic plants has focused attention on this new technology and its potential consequences [Snow and Moran Palma, 1997].

The essence of the issue with the ecological impact of bioengineered plants is the following: 1) it is not the techniques themselves that may lead to environmental or agricultural problems, but rather the phenotypic traits that results; 2) the need for concern varies greatly depending on the type of trait(s) transferred and whether the transgenic organism can persist in free-living populations or hybridize with non-transgenic populations of the same or related species; 3) the understanding of the long term effects of the commercialization requires an interdisciplinary approach; and 4) most of the thousands of small-scale field tests of transgenic plants have not been designed to investigate the ecological risks associated with widespread commercialization [Wrubel et al., 1992]. The dangers of increased weediness depend less on the type of gene transfer method involved in crop

improvement than on the biology of the gene transferred and how it is expressed in the hybrid [Tiedje et al., 1989]. The significance of gene escape will vary with the biology of the plant donor, the wild recipient, and the introduced gene. In regards to the crop donor, primary risks will probably come from crops: 1) that have undergone little domestication because there would be minimal ecological and reproductive divergence from the wild progenitors [Ellstrand and Hoffman, 1990]; 2) grown sympatric with wild relatives (e.g. centers of origin) or cross-compatible species (or genera); 3) that have biotypes or related taxa that are already aggressive weeds; 4) that can also be weeds themselves; and 5) outcross with some degree of self-incompatibility.

Plants such as turf, forages, rangeland, and bioremediation grasses that have undergone little domestication and often have wild relatives growing in sympatry [Arriola and Ellstrand, 1996; Giddings et al., 1997a; Ellstrand and Hoffman, 1990] and/or can be weeds outside of cultivation and in other crops, are particularly at risk of spreading transgenic DNA. Bermuda grass [*Cynodon dactylon* (L.) C. Persoon] is an important perennial forage and turfgrass, but it is also, in many areas of the United States, is one of the worst weeds. If a gene that would confer a selective advantage were introduced into a cultivar (by either biotechnology or conventional breeding) and the gene escaped into the weedy populations, the immediate economic and ecological impact could be significant [Ellstrand and Hoffman, 1990]. Giddings et al. [1997a] reported that the major wind-pollinated crops in the United Kingdom that are cross-compatible with native and feral populations and that are likely to flower on a

wide scale are the forage grasses. Forage rygrasses (*Lolium perenne* L. and *L. perenne* var. *aristata* C. von Willdenow (syn = *L. multiflorum* J. de Lamarck)are widely cultivated cross pollinating forage crops, which readily outcross with wild and feral populations and occasionally with fescue species (*Festuca* spp.). *Lolium-Festuca* hybrids (x *Festulolium* Ascherson & Graebner) can be fertile and have an ability to backcross with either of the parents.

These problems are not just theoretical, because within highly domesticated crops, crop-weed hybridizations have occurred, leading to the evolution of aggressive weeds [Barrett, 1983], and demonstrating that the hazards created by these hybridizations occur in nature and are not unique to genetic engineering. These weeds are difficult to control because they share so many traits with the crop. Examples of this can be found in cultivated sorghum (*Sorghum bicolor* (L.) C. Moench), pearl millet (*Pennisetum glaucum* L.), radish (*Raphanus sativus* L.), and sugar beets (*Beta vulagaris* L. subsp. *vulgaris*). Johnsongrass (*Sorghum halepense* (L.) C. Persoon) is known to be an interspecific hybrid descendant of *S. bicolor* and *S. propinquum* (K. Kunth) A. Hitchcock [Paterson et al., 1995] and is considered to be a primary noxious weed worldwide [Holm et al. 1977]. Its hybridization with cultivated sorghum resulted in the evolution of invasive weedy biotypes [Baker, 1972; Arriola and Ellstand, 1996]. A similar case happened with pearl millet. A common noxious weed (*P. sieberanum* (Schlecht.) Stapf & Hubbard) of pearl millet in Africa is also a biotype of pearl millet. This weedy biotype, which mimics pearl millet, evolved through the hybridization of pearl millet with its wild progenitor (*P.*

violaceum (Lam.) Rich.) [Brunken et al., 1977]. In California during the nineteenth century, cultivated radish hybridized with an introduced weed, *Raphanus raphanistrum* L.) to create a new weed known as wild radish [Panetsos and Baker, 1967]. More recently, a new weed evolved in France when sugar beets (*Beta vulgaris* L. subsp. *vulgaris*) hybridized with a subspecies from the Mediterranean [*B. vulgaris* ssp. *maritima* (L.) Archang.] [Boudry et al., 1993]. These examples also demonstrate that new weeds can evolve quickly.

The concern regarding the transfer of alien genes into local populations that results in non-weedy populations becoming weedy or weedy populations becoming more weedy is not the only issue. The other ecological impact could be the contamination of the native gene pool, which could have a variety of possible consequences [Kareiva et al., 1994]. For example, the extinction of wild rice in Taiwan has been attributed in part to gene flow from cultivated rice to wild rice [Kiang et al., 1979; Oka, 1992]. So, the full impact of gene escapement on natural populations must be considered. If the genes and transgenic plants could be confined with certainty to the agricultural settings for which they were designed, their negative ecological and agricultural impacts would be greatly reduced. Unfortunately, pollen and seeds are dispersed, and the door is open to a cascade of environmental problems, such as, an increase in weediness and invasiveness that could threaten extinction of native plants, contamination of gene pools, and the disruption of innate plant communities [Ellstrand, 1988]. Since many of these problems begin with gene escape through the pollen, the logical first step in a

biotechnology risk assessment is the quantifications of pollen movement and the intraspecific, interspecific and intergeneric hybridization possibilities between transgenic crops and non-transgenic populations. If pollen is found to travel great distances, pollen viability becomes an issue, and determining how far viable pollen travels under various environmental conditions must be assessed.

The dispersal distance of pollen from a source is dependent on a number of factors, such as wind speed and turbulence, height, and duration of pollen release [Okubo and Levin, 1989], and other climatic conditions (e.g. relative humidity, temperature, and air pressure). Giddings et al. [1997a,b] conducted a series of experiments on pollen dispersal for determining the risk of introducing genetically modified wind-pollinated forage grasses. Pollen dispersal was studied from a perennial ryegrass (*Lolium perenne* L.) source using pollen traps. Giddings et al. [1997a] reported that the most striking feature reoccurring throughout their analysis was the high variability of pollen deposition. They found a large amount of variation in pollen dispersal over time and to traps of different orientations. Twelve data sets were collected and were used to test Bateman's equations [Bateman, 1947] for the wind dispersal of pollen. Batman's equations were found not to be useful for describing dispersal over distance and clearly needed to be modified to take factors such as wind direction into account. Giddings et al. [1997b] studying the influence of wind direction on pollen dispersal, found that for 11 of the 12 data sets, the new equation fit significantly better than Bateman's original equations. They also produced 15 data subsets from the mean wind directions to test

Bateman's equations for dispersal downwind from a pollen source. These equations fit only four of the data subsets. They found that the amount of pollen deposited does not always decrease smoothly with increasing distance from the source. Three of the 12 data sets they analyzed had an increase in pollen deposition with distance; more pollen was collected at 80 m than at 60 m. This highlights the danger of assuming that deposition decreases smoothly over distance varying only with wind direction. Pollen clouds are taken high into the atmosphere, moved, and deposited during times of calm. Pollen could possibly be transported considerable distances from the source, and so could be important in terms of transgene spread. Wind speed and turbulence were expected to be important factors affecting this process. However, models involving such additional parameters would be complex and would probably show chaotic dynamics, making prediction difficult. In bentgrass production fields, one form of turbulence often observed are 'whirl winds' that move across a field and carry pollen high into the atmosphere. Since the prediction of pollen dispersal involving this kind of turbulence is extremely difficult and currently no models are known to exist that accurately predict the effects of these complex parameters, any prediction models will have to be assumed that there will be a slow decline in pollen dispersal with increasing distance from a source. Traditionally, pollen dispersal was assumed to follow a bivariate normal distribution [Wright, 1943; Haldane, 1948]. However, pollen dispersal distributions from plants are strongly leptokurtic [Levin and Kerster, 1974; Thompson et al., 1999] and this has led to the suggestion that a exponential power function [Bateman, 1947; Kareiva, 1994] be used to describe

pollen distribution. Since climatic parameters will differ greatly from region to region and have an effect on pollen movement, viability, and frequency of successful fertilizations, research must be conducted where the crop will be commercially cultivated.

Giddings [2000] reported on *Lolium perenne* pollen dispersal using a Gaussian plume model, which takes into account distance and wind direction. The model was used to calculate, using integration, possible pollen deposition onto small conspecific populations one kilometer from the source. Initially the source and recipient populations were 2-m in radius (the same as the source the data is based). The percentage of immigrant pollen was compared for six different sets of parameter values previously estimated from pollen-dispersal experiments [Giddings et al., 1997a,b]. In the 2-m radius plots 0.008 to 3.52 % of the pollen deposited on the downwind "recipient" population was from the donor "transgenic" population. The source size was then scaled up to 10.24 ha (25.3 ac) to simulate what might happen if transgenic ryegrass was grown on a large scale When the source size was scaled up to 10.24 ha, the amount of pollen deposition increased to 29.74 to 99.64 % downwind from the source. Recipient populations centered 90° to the mean wind direction received 4.90 to 51.12 % of the pollen from the source population. Because of the potential for long-distance pollen movement, the use of 'guard rows' around transgenic crops to prevent gene flow out of the field seems unlikely to be effective at preventing pollen dispersal at some distance from the crop.

The study of "gene-transfer or gene-flow at the population level is a fundamental issue to risk assessment, because it represents an avenue by which

engineered genes may escape from cultivated fields" [Kjellsson et al., 1997]. In order for gene-transfer to occur, the following events must take place: outcrossing and introgression. First outcrossing and successful fertilization of a non-transgenic ovule by pollen carrying the transgene must occur to produce a hybrid. So, out-crossing is a prerequisite to gene-transfer. The rate of outcrossing is dependent on the type of pollination and breeding system of the transgenic species. Creeping bentgrass has the following characteristics: small flowers, small or lacking perianth, no chemical attractants, anthers and stigmas exposed, production of copious amounts of small pollen grains and is wind pollinated [Kjellsson et al., 1997]. The breeding system of creeping bentgrass is predominantly cross pollinated and usually highly self incompatable (or self-sterile) [Björkman, 1960]. Both wind pollination and out-crossing would indicate a high outcrossing potential. Ellstrand and Hoffman [1990] reported a colonial bentgrass (*Agrostis capllaris*) gene flow of >1% at 8,000 m (26,304.64 ft) estimated by paternity analysis.

The second event for gene-transfer to occur is the introgression of the transgene. Introgression or introgressive hybridization occurs when outcrossing results in a stable incorporation of the transgene into the non-transgenic population. Of course, the rate of introgression is expected to be significantly higher in intra-specific hybrids than in inter-specific and inter-generic hybrids. The stability of the latter two groups of hybrids will depend on longevity (annual vs. perennial) or persistence, and cytogenetic behavior of the hybrids. Perennial hybrids will persist longer, increasing the possibility of producing progeny through

backcrossing or chromosomal doubling. Polyploidy also increases the chance of some fertility in the hybrid through homologous genomes shared between different taxa and so would allow the possibility of backcrossing and possibly result in fertile progeny.

Creeping bentgrass is cool season grass used for high quality putting greens, fairways, bowling clubs, and for closely cut lawns. The first transgenic turfgrass species to be requested for deregulation by APHIS will be a creeping bentgrass transformed for herbicide resistance since it is one of the highest valued turfgrass seed crops on the market.

However, successful commercialization depends on the crop being deregulated by USDA-APHIS, which requires a description of the known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant risk than the unmodified organism from which it was derived, including but not limited to: 1) plant pest risk characteristics; 2) disease and pest susceptibilities; 3) expression of the gene product; 4) new enzymes; 5) changes to plant metabolism; 6) weediness of the regulated article; 7) impact on the weediness of any other plant with which it can interbreed; 8) agricultural or cultivation practices; 9) effects of the regulated organism on non-target organisms; 10) indirect plant pest effects on other agricultural products; 11) transfer of genetic information to organisms with which it cannot interbreed; and 12) any other information which the Administrator believes to be relevant to a determination (Regulation 7CFR340.6C(4)).

Creeping bentgrass is an out-crossing and wind pollinated, stoloniferous, perennial species. "Oregon

produces nearly all of the bentgrass seed grown in the United States. Predominantly a Willamette Valley crop, bentgrass seed is exported in large quantities to Europe and also to the central and northern states for use in turf mixtures. This grass is widely used on golf courses throughout the world" [Young et al., 1997]. During the 1999 season, bentgrass was grown on 11,602 acres: 7,296 acres of creeping bentgrass; 4,300 acres of colonial and dryland bentgrass; and 83 acres of velvet bentgrass [OSCS, 1999]. In 1999, Oregon produced 4,778,000 lbs. of creeping bentgrass and 1,596,000 lbs. of colonial and dryland bentgrass [Young, 2000].

Creeping bentgrass has the potential to be the first perennial (stoloniferous), wind pollinated, outcrossing transgenic crop to be grown adjacent to naturalized and native populations of cross-compatible perennial relatives and native species. These are traits that can increase the risk of outcrossing, persistence, and introgression of alien genes into an adjacent population. However, the bulk of most of the risk assessment work conducted on transgenic plants has been on annual and/or self-pollinating crops. The potential risks from the commercialization and large-scale seed production of these types of transgenic crops is unknown. Research must be conducted to adequately assess the ecological and economic risks associated with introducing transgenes in a seed production situation. As increased research progresses in producing transgenic creeping bentgrass and as the release of a genetically engineered bentgrass cultivar draws closer, questions regarding pollen flow and gene introgression into local populations must be answered to insure environmentally and agriculturally safe introduction of transformed products.

Agrostis stolonifera has been documented as forming natural hybrids with the following species: 1) *A. canina*; 2) *A. capillaris*; 3) *A. castellana*; 4) *A. gigantea*; 5) *A. mertensii* Trinius; and 6) *A. vinealis* [Murbeck, 1898; Weber, 1920; Fouillade, 1932; Philipson, 1937: Stuckey and Banfield, 1946; Paunero, 1947; Davies ,1953a,b; Jones, 1953, 1956a,b,c; Bradshaw, 1958; Bradshaw, 1959; Björkman, 1960; Widén, 1971; Suckling and Forde, 1978; Bradshaw, 1975; Tutin, 1980; Edgar and Forde, 1991; and Forde, 1991]. Some of the interspecific hybrids are so common in nature that they have been given scientific names. The following interspecific hybrids have been formally named: 1) *A.* x *murbeckii* Fouillade (*A. stolonifera* x *A. capillaris*); and 2) *A.* x *bjoerkmanii* Widen (*A. capillaris* x *A. gigantea*)

A few studies have been published on artificial interspecific hybridization in *Agrostis*. The following experimental interspecific crosses have been made:

1) creeping bentgrass x *A. vinealis* [Björkman, 1960; Jones, 1956a, 1956b]. The seed set and pollen fertility were poor. At least 7 chromosomes remained unpaired in all cells; the maximum pairing was $1_{IV}5_{III}1_{II}7_{I}$. One genome of *A. stolonifera* showed partial homology with those of *A. vinealis*.

2) creeping bentgrass x *A. capillaris* (syn =*A. tenuis* Sibth.) [Björkman, 1960; Edgar and Forde, 1991; Davies, 1953a,b; Jones, 1956b, 1956c]. The seed set and pollen fertility were poor in one study, but *Agrostis capillaris* x *A. stolonifera* hybrids had 41.0% pollen fertility in another study. These hybrids were stoloniferous, vigorous, and apparantly long-lived in pastures [Forde, 1991].

Agrostis stolonifera and *Agrostis capillaris* probably have one ancestral diploid type in common and show good homology in one pair of their genomes and partial homology between the other one. The inter-genome pairing of *A. capillaris* is responsible for the fluctuation in pairing in the hybrids, which was also responsible for the fluctuation in pollen fertility [Jones, 1956b].

3) creeping bentgrass x *A. gigantea* Roth [Davies, 1953a,b; Jones, 1956c]. The seed set was 19.9 seeds/panicle and pollen fertility was 0 to 30% [Jones, 1956c]. The stable pairing and constant occurrence of seven univalents suggested that they constituted two pairs of highly homologous genomes, and the third show little homology with the others; the latter genome was possibly derived from an unknown ancestor. Davies [1953a] reported that the F_1 hybrids were quite fertile.

4) *A. capillaris* x *A. gigantea* [Davies, 1953a,b; Jones 1956c]. The seed set of the hybrids was 39.3/panicle and pollen fertility was 41 to 55%. The F_1 hybrids were as fertile as their parents on the basis of number of seeds per panicle under conditions of open pollination. The stable pairing and constant occurrence of seven univalents suggested that they constituted two pairs of highly homologous genomes, and the third showed little homology with the others; the latter genome was probably derived from the hexaploid parent (*A. gigantea*). The F_2 hybrids (inter-pollination of F_1's) had a pollen fertility of 53.3 to 62.8%. Back-crosses of the F_1 with A. capillaris (*A. capillaris* x *A. gigantea*) x *A. capillaris*) had a pollen fertility of

20.6 to 75% [Jones, 1956c]. Davies [1953a] reported that the F_1 hybrids were quite fertile.

5) *A. capillaris* x *A. vinealis* and (*A. capillaris* x *A. vinealis*) x *A. vinealis* [Jones, 1956b]. The F_1 hybrids between *A. capillaris* and *A. vinealis*, the F_2 generation, and backcrosses of the F_1's with *A. vinealis* were as fertile as the parents and were indistinguishable from *A. vinealis* at meiosis. The quadrivalent pairing sheds light not only on the interspecific relationships but also on the nature of *A. capillaris* itself. The purely bivalent pairing in *A. capillaris* disguised the fact that its genomes showed appreciable homology.

6) *A. castellana* x *A. capillaris* [Forde, 1991]. The hybrids were as fertile as the parents. The pollen fertility was 92.3%. The 11 F_1 hybrids were allowed to interpollinate with *A. capillaris* and *A. castellana* collections. The resulting progenies were vigorous and highly fertile, and displayed various combinations of the parental characters.

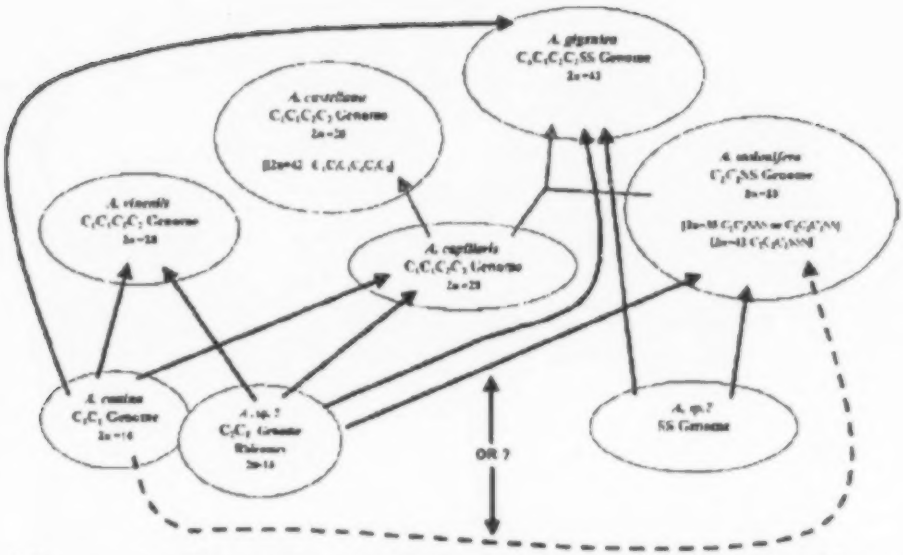

Figure 1. Genomic phylogency of *Agrostis stolonifera* complex.

The hybrids were reported to have varying degrees of fertility, from sterile to as fertile as the parents. As would be expected, various genotypes differed in fertility, which mandated the use of multiple genotypes in crossing experiments. Most of the hybrids were vigorous regardless of fertility. The hybridization studies of Davies [1953a,b], Jones [1956a,b,c], Björkman [1960], and Forde [1991] clearly demonstrated that *A. canina*, *A. capillaris*, *A. castellana*, *A. gigantea*, *A. stolonifera*, and *A. vinealis* form a complex of interpollinating, cross-compatible species that readily cross when the species are sympatric (Fig. 1). *Agrostis stolonifera* (C_2C_2SS) is a allotetraploid, in which both of its genomes are highly homologous with two genomes of *A. gigantea* ($C_1C_1C_2C_2SS$). *Agrostis stolonifera* and *A. capillaris* ($C_1C_1C_2C_2$) have one genome in common. *Agrostis capillaris* is a segmental allotetraploid, in which both of its genomes are highly homologous with two genomes of *A. gigantea* ($C_1C_1C_2C_2SS$). Davies [1953b] concluded

that both *A. capillaris* and *A. stolonifera* have something in common with *A. gigantea*, and they were involved in its evolution, or they at least have common origins with it. Widen [1971] also hypothesized that *A. gigantea* may have arisen from the fusion of C_1C_2S gametes of *A.* x *murbeckii* (the interspecific hybrid between *A. stolonifera* and *A. capillaris*). *Agrostis capillaris* also has a close chromosomal relationship with *A. vinealis* and *A. castellana*. *Agrostis vinealis* possibly evolved through introgression of a non-rhizomatous autotetraploid of *A. canina* with a rhizomatous plant of an *A. capillaris* type.

Intergeneric hybrids have also be reported between *Agrostis* and *Polypogon* [Björkman, 1960]. *Polypogon* species will hybridize with creeping bentgrass: 1) *Polypogon monspeliensis* (L.) R. Desfontaines, the hybrid between these two taxa occurs frequently enough that taxonomists have given it a name, x *Agropogon littoralis* (J.E. Smith) C.E. Hubbard; 2) *Polypogon viridis* (Gouan) Breistr., named x *Agropogon robinsonii* (Druce) Meldris & D. C. McClint.; 3) *P. fugax*; [Björkman, 1960]. Tutin [1980] hypothesized that *Agrostis parlatorei* Breistr. and *A. moldavica* Dobrescu & Beldie are perhaps derived through the hybridization of *A. castellana* and *Polypogon viridis*.

This information is relevant, because several of these *Agrostis* species occur in the Willamette Valley. "Information on the amount of out-crossing among Agrostis species does not exist for turfgrass seed production and managed turfgrass areas" [Johnson et al., 1999]. A total of 19 species have been documented in Oregon [Harvey, In Prep.]. Of the 19 species, 12 are reported to occur in the Willamette Valley and can be

found in bentgrass seed production areas. Six of the 12 are naturalized species: *A. canina*, *A. capillaris*, *A. castellana*, *A. stolonifera*, *A. gigantea*, and *A. vinealis*. These six species are not only used commercially, but also are considered weeds in other crops. Of the remaining 12 species that are native to the area, the following six are known to occur in the Willamette Valley: *A. diegoensis* Vasey, *A. exarata* Trinius, *A. hallii* Vasey, *A. longiligula A. Hitchcock*, *A. oregonesis* Vasey, and *A. scabra* Willdenow. Carlbom [1966] in a biosystematic study of nineteen species of *Agrostis*, native to the Pacific states and all belonging to sect. *Trichodium* (Michx.) Trinius, reported on the reproductive biology of some of these species by conducting experiments on seed set in controlled self-pollinations. He reported that *A. exarata* was autogamous (self-compatible); *A. diegoensis*, *A. hallii*, and *A. oregonesis* were allogamous (self-incompatible or cross fertilized); *A. scabra* was both, depending on ecotype; and *A. longiligula* was not tested. Putative natural hybridization and introgression were observed between *A. diegoensis* and *A. hallii*; *A. diegoensis* and *A. pallens*. The outcrossing of these species with the six naturalized species was not studied.

Three species of *Polypogon* are also documented in Oregon: *P. monspeliensis* (L.) Desfontaines, *P. interruptus* Kunth, and *P. viridis* (Gouan) Breistroffer.

This objectives of this research were to study: 1) intra-specific gene movement; and 2) interspecific gene introgression and stability of the hybrids. The use of transgenic plants offers a unique opportunity to test and quantify pollen movement distances for creeping bentgrass using a dominant marker system.

MATERIALS AND METHODS

Transgenic Creeping Bentgrass

The transgenic plants that were used in this study were transformed by microprojectile bombardment at Michigan State University, by Dr. C.-A. Lu [1996] in Dr. Mariam Stricklen's lab. The genes were introduced on a commonly used plasmid vector, pUC #19. The plants were genetically engineered for tolerance to the herbicide glufosinate through the expression of the bar gene derived from *Streptomyces hygroscopicus*, which encodes the enzyme phosphinothricin acetyl transferase (PAT). PAT inactivates the herbicide phosphinothricin (PPT) by acetylation, which converts the active compound to a herbicidally-inactive product [Murakami et al., 1986; Thompson et al., 1987; Vasil, 1996]. PTT is the active ingredient in glufosinate or bialaphos. Glufosinate is a non-selective herbicide that inhibits the enzyme glutamine synthase. The inhibition of this enzyme allows ammonia levels to increase to phytotoxic levels, leading to cell death [Tachibana et al., 1986a,b; Devine et al. 1993]. Because higher plants cannot naturally convert these herbicides to inactive products, transformation of crops with the bar gene may allow for complete weed control and result in little damage to the transformed plant. Moreover, the presence of this pathway in bacteria, but not in plants, is indicative of a low potential for the development of resistance [Smeda and Vaughn, 1997]. The noncoding DNA regulatory sequences that control expression of the introduced genes are the CaMV 35s promoter and the nos terminator from *Agrobacterium tumefaciens* T-DNA. A proteinase inhibitor gene (*pin*-2) derived from *Solanum tuberosum*, was also part of the gene

construct, but this gene has not been shown to affect the phenotype of the bentgrass.

Of the 60 transformants recovered, all were sterile (either did not flower or if flowering culms were produced, they failed to produce viable reproductive organs), except one. This plant flowered and produced viable pollen and ovaries and was successfully crossed with Seaside II creeping bentgrass in the greenhouse out Michigan State University by Dr. Scott Warnke. Approximately 1,000 progeny were recovered. These prospective transformants were screened for herbicide tolerance with a 6X label rate (label rate: 24 oz/ac) of Ignite®, resulting in 480 herbicide tolerant transformed seedlings. These plants were sent to Oregon and 286 were planted into a nursery. The other 194 plants died en route to Oregon due to freezing temperatures.

Lee et al. [1996] conducted herbicide tests on transgenic creeping bentgrass with Herbiace®, a commercial formulation of bialaphos released in 1978 by Meijii Seika Kaishya, LTD., Tokyo. The herbicide rates were established with control plants, and were applied at the commercial rate of 0.75 lb AI/ac (1 x the field rate). The transgenic plants were resistant to 5x the field rate of Herbiace®. Lee and Day [1996] reported that one-month-old bentgrass plants, transformed with the bar gene, were unaffected by a 5x field rate of Herbiace® (2 mg/mL). No control plants survived the herbicide treatment after 10 days, while the transgenic plants were undamaged and as healthy as the control plants. Zhong et al. [1996] sprayed 38 independent transgenic lines with 1.2% Ignite® (label rate: 2.4 g/L of glufosinate ammonium, 1.50 L/ha). This rate killed the control plants within 10

days and 37 of the 38 transgenic lines showed no obvious damage. Zhong et al. [1996] also found from evaluating the herbicide resistance levels of three independent events that the levels of PAT activity were different. The LD_{50} values (lethal dose that caused 50% of plant death) of the three tested transgenic lines were about 20, 30, or 40 times higher that that of non-transgenic plants. These tests showed that the labelled rate of glufosinate herbicides are sufficient to kill non-transgenic plants and demonstrated that the transgenic plants have a high level of resistance to PPT.

Table 1. Description of 1998 transects.

Transect Acronym	Description of Transect	Number of plants planted	Number of plants actually harvested
LC	272.5 ft (83.1 m) circle with 100 ft (30.48 m) spacing	17	13
SC	109 ft (33.2 m)circle with 50 ft (15.24 m) spacing	14	13
NET	NE line from edge to 244 ft (74.4 m). 10 ft (3.05 m) spacing for first 120 ft (36.6 m) and then 20 ft (6.1 m) spacing	17	17
SWT	SW line from edge to 300 ft (91.4 m). 10 ft (3.05 m) spacing for first 120 ft (36.6 m) and then 20 ft (6.1 m) spacing	21	21
RNE	NE Transect through rye. 5 ft (1.52 m) spacing	9	5

Transect Acronym	Description of Transect	Number of plants planted	Number of plants actually harvested
RSW	SW Transect through rye. 5 ft (1.52 m) spacing	9	6
RI	Transect inside rye border 10 ft (3.05 m) spacing	22	22
Row 10	Row 10 is on N side in transgenic nursery, Non-transgenic plants	32	29
RM	Transect in the rye border. 6 ft (1.8 m) inside the rye and 10 ft (3.05 m) spacing	42	40
RO	Transect around the outside of the rye border, 10 ft (3.05 m) spacing	54	45
Total		237	211
Agrostis spp. into nursery	*Agrostis* spp. planted	13	13
TOTAL		250	224

Non-transgenic Creeping Bentgrass

The non-transgenic creeping bentgrass cultivar used in this study was Penn *A-1*. This cultivar was chosen because the plants were similar in age and maturity to the transgenic plants. Creeping bentgrass has a maturation requirement to reach optimum flower production and must be vernalized. Generally plants begin flowering their second year after vernalization. The plants were taken from a two year old production field (planted in 1997), which was the same age of the transgenic plants. The field was 4 mi south of the

study site. New plants for the transects were dug each year for the study.

The Penn A-1 plants were evaluated for tolerance to glufosinate to establish the rate for screening seedlings containing the bar gene. Five different non-transgenic genotypes (including Penn A-1) of creeping bentgrass and one genotype of colonial bentgrass were screened with Finale®. Approximately 2,000,000 seedlings were tested for each genotype, with two of the genotypes tested twice (Penn A-1 and Penn A-2). A total of ± 14,000,000 seedlings of creeping bentgrass and 2,000,000 seedlings of colonial bentgrass were sprayed twice with a 5.7 L/.4 ha (6 qts/ac) rate of Finale® and no survivors were found within 14 days. Transgenic bentgrass seedlings were not damaged with this rate.

Experimental Design Of Transects for Infra-specific Gene Flow

Approximately 250 non-transgenic bentgrasses were planted in transects around the 286 transgenic bentgrass plants [36 x 128 ft nursery (≈ 0.1 ac or 0.04 ha)] in 1998 and 1999. This ratio of transgenic to non-transgenic plants was sufficient to detect the spread of the bar gene. Gliddon [1999] pointed out that the vast majority of pollen dispersal studies involving marker genes have the transgenic organism as a small minority of the total organisms in the design, making it difficult to detect the spread of the marker gene in relation to the probability of recovering the non-marked gene. If the marker is represented by 1% of the total organisms, even if its spread is uniform across the entire experimental area, it will only be recovered in 1% of samples. "This fault of experimental design could well account for the very small distances that

have been reported for the spread of GMO's [e.g. Scheffler et al., 1993]" [Gliddon, 1997].

In 1998, the following transects were established (Table 1, Figure 2): 1) two circles around the nursery at 109 (33.2 m) and 272.5 ft (83.1 m) with plants spaced at 50 ft (15.24 m) and 100 ft (30.48 m), respectively; and 2) two line transects aligned with prevailing winds (NE) with one transect NE and the SW of the transgenic nursery. The NE transect extended 244 ft (74.4 m) from the NE edge of the nursery and the SW transect extended 300 ft (91.4 m) from the SW edge of the nursery. Plants in the line transects were spaced 10 ft (3.048 m) apart for the first 120 ft (36.6 m), then spaced 20 ft (6.1 m) after. The initial length of the transects was based on Oregon Seed Certification isolation distances, which is 165 to 300 ft (50.3-91.4 m) (depending on field size) for certified seed production. To test the effectiveness of cereal rye (*Secale cereale* L.) as a pollen barrier, non-transgenic plants were planted around the inside of the transgenic nursery, six feet (1.8 m) inside the cereal rye, on the outside of the cereal rye border, and through the NE and SW corners of the cereal rye. One hundred sixty-eight plants were placed in or around the cereal rye border.

Figure 2. Overview of transects for pollen travel study.

In the 1999 the experimental design was similar to that of 1998 with the exception of the following (Figure 3): 1) two additional line transects (SE and NW), orthogonal to the prevailing winds were added; 2) the length of the line transects were increased, where possible, to the following: a.) SW transect, 978 ft (298.1 m); b.) NE transect, 268 ft (81.7 m); c.) SE transect, 612 ft (186.5 m); and d.) NW transect, 319 ft (97.2 m). Non-transgenic were also planted around the transgenic nursery both years; 3) Plants in the line transects were spaced 20 ft (6.1 m) apart for the first 300 ft (91.4 m) and then every 10 ft (3.048 m) apart after; 4) the plants

in the 272.5 ft (83.1 m) radius transect were spaced every 50 ft (15.24 m), not 100 ft as in the previous year; 5) only 20 non-transgenic plants were planted around the outside of the transgenic nursery—5 plants on each side; and 6) Row 10, the non-transgenic row of plants in the transgenic nursery, was the only non-transgenic plants in the nursery.

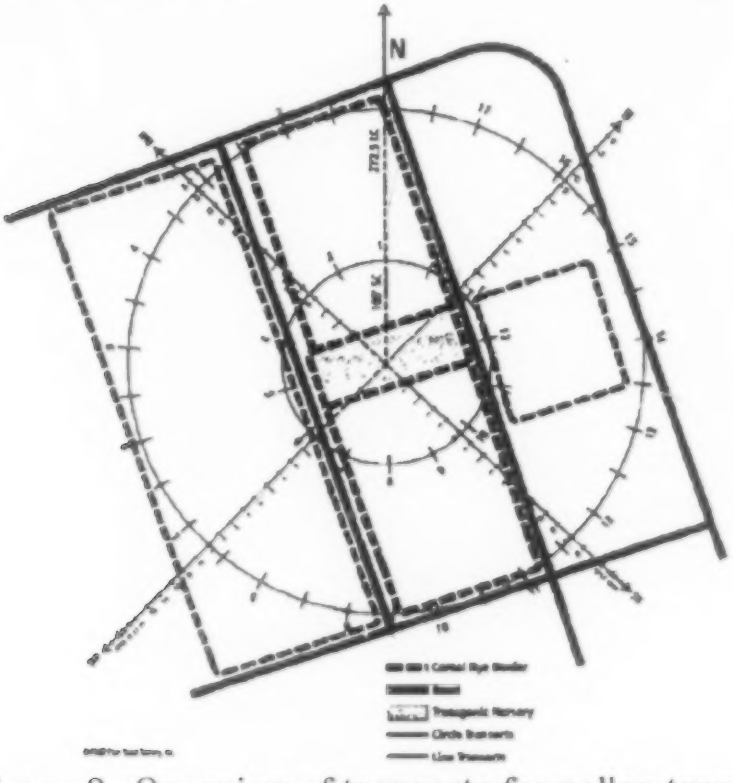

Figure 3. Overview of transects for pollen travel study.

Non-transgenic plants were planted into the transects during February and March of each year. Once the plants finished flowering, inflorescences were enclosed in hybridization bags. Any remaining, unbagged, inflorescences were cut and burned to prevent any contamination. The inflorescences were then harvested and the non-transgenic plants were killed with herbicide (Roundup®) and then burned;

they were replanted each year. The removal of non-transgenic plant prevented the contamination of this plant from any transgenic seed that may have been produced, fallen to the ground, germinated and grew in with the non-transgenic plant. If this occurred, then this plant would be producing transgenic pollen along the transect.

The harvested inflorescences were dried in the greenhouse. Once dry, seeds from each non-transgenic plant were planted and screened in greenhouse for herbicide resistance; 1000+ seeds were planted in order to get 1,000 seedlings to be screened. The seedlings were sprayed 2 to 3 times with Finale™ or Rely® (which has now replaced Finale™) once they reached the 3 to 4 leaf stage, with a rate of 5.7 L/.4 ha (6 qts/ac). This rate is listed for plants 8 in (20.32 cm) or taller. This rate has been tested on five different non-transgenic genotypes of creeping bentgrass and one genotype of colonial bentgrass. Approximately 2,000,000 seedlings per genotype were tested, with two of the genotypes tested twice. A total of ± 24,000,000 seedlings of creeping bentgrass and 2,000,000 seedlings of colonial bentgrass were sprayed twice with a 5.7 L/.4 ha (6 qts/ac) rate of Finale™ with no survivors. Whereas, transgenic bentgrass plants were not damaged with this rate.

Screening seedlings with the high labelled rate of glufosinate (5.7 L/.4 ha (6 qts/ac) for Finale™) will sufficiently kill the plants and only those plants with the functioning bar gene can survive that rate, even though a low level of resistance to glufosinate is sometimes seen.

The number of survivors and the number of dead were counted. A sample of the survivors were sent to

a biotechnology lab to confirm the presence of the bar gene using PCR and Southern Blot analysis. Once the percentage of resistant to non-resistant seedlings was determined, the data were then analyzed with Graphpad Prism® non-linear regression software. The curve that best fit the data was a 'Top to Zero One Phase Exponential Decay' Model. This allowed for the prediction of the percent recovery of the transgene over distance.

Figure 4. 1998 transgenic bentgrass gene flow

Inter-specific Gene Flow

Plants were placed in the transgenic nursery next to plants with a similar phenology. Accessions of *A. canina*, *A. capillaris*, *A. castellana*, *A. curtissii*, *A. gigantea*, in 1998, and *A. pallens* and *A.* sp. eastern Oregon, in 1999, were planted in the transgenic nursery prior to flowering and allowed to interpollinate. Seed was collected from these accessions, planted, and screened for herbicide resistance as described above.

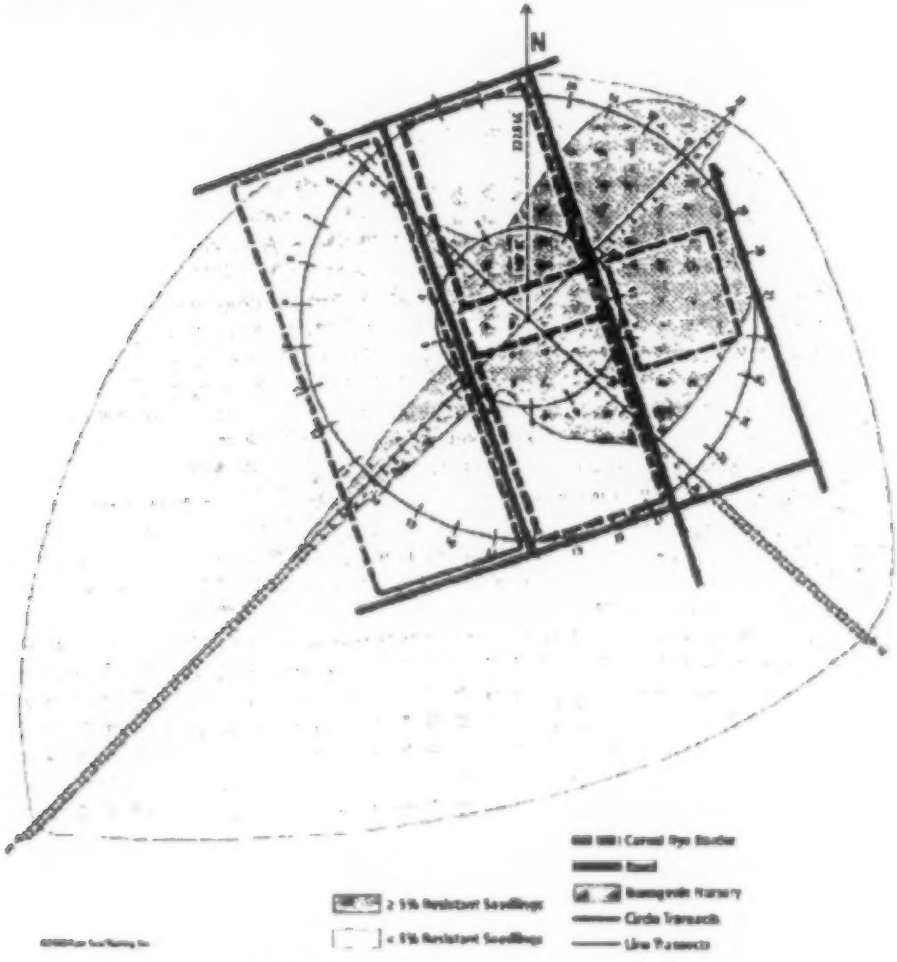

Figure 5. 1999 transgenic bentgrass gene flow.

RESULTS AND DISCUSSION

Intra-Specific Gene Flow

In 1998, >0.02 % transgenic plants were recovered at the ends of both the NE (244 ft (74.4 m) and SW (300 ft (91.4 m) transects, as well as, from most of the points along the circle transects (Figure 4). In 1999, >0.02 % transgenic plants were recovered at the following distances: 1) NE transect, 268 ft (end of transect); 2) SW transect, 958 ft; 3) NW transect, 319 ft; and 4) SE transect, 612 ft from edge of transgenic nursery (Figure 5).

The distribution of the data was determined to be strongly leptokurtic and not normally distributed, which is congruent with other pollen distribution data (as discussed in the Introduction). The data were then analyzed using non-linear regression, since the goal of regression was to find a curve that best predicted Y from X, an exponential decay model was determined to fit the data well. Using this model, the following distances were predicted for transgenic pollen introgression to the 0.02 % level. In 1998, along the SW transect, transgenic pollen traveled 3,500 ft (1,066.8 m) and along the NE transect, it traveled 4,296 ft. (1,309.4 m) (Figures 6-7). In 1999, the transgenic pollen was estimated to have traveled 1,022 ft (331.5 m) to the SW, 1,892 ft (575.1 m) to the NE, 861 ft (262.4 m) to the NW, and 1,022 ft (331.5 m) to the SE (Figures 8-11). A diagrammatic representation of predicted pollen flow based on the exponential decay model results for 1998 and 1999 pollen flow data can be seen in Figures 12 and 13.

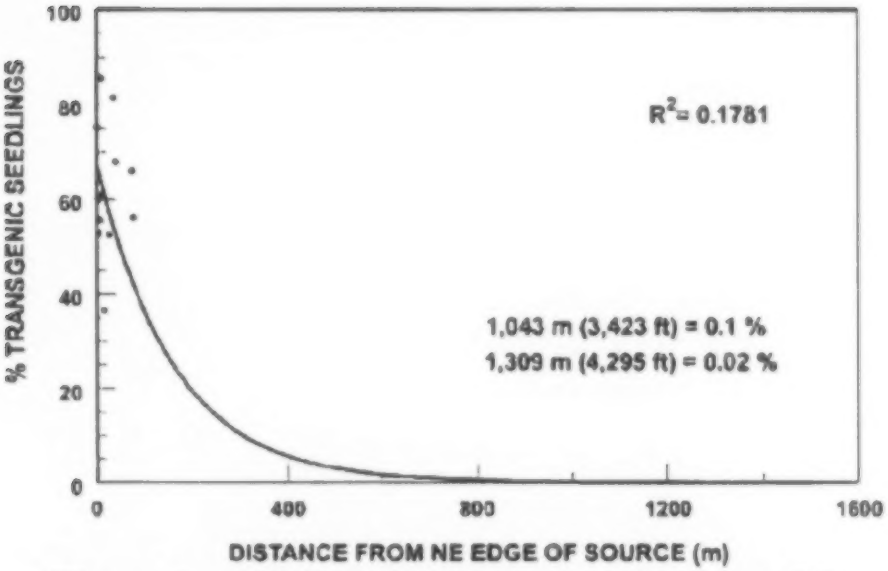

Figure 6. 1998 Transgenic pollen flow along NE transect.

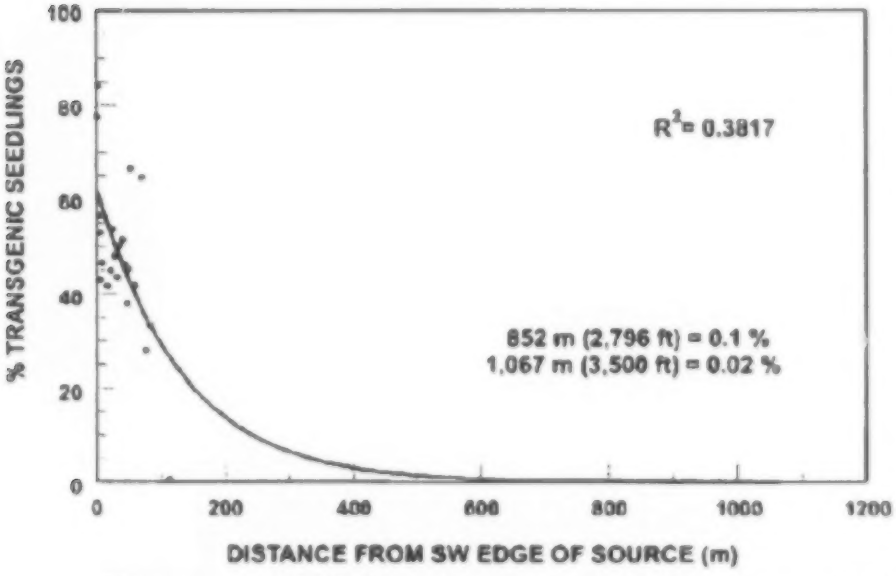

Figure 7. 1998 Transgenic pollen flow along SW transect.

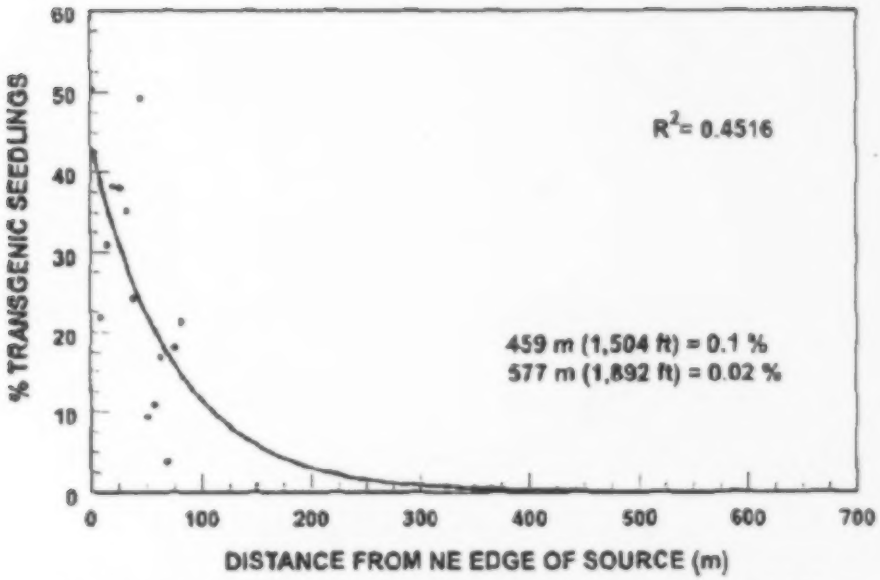

Figure 8. 1999 Transgenic pollen flow along NE transect.

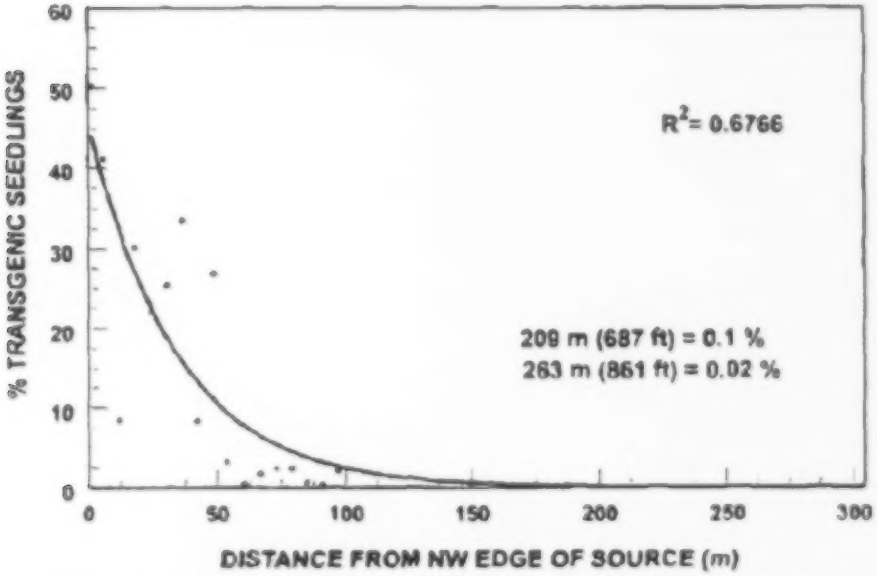

Figure 9. 1999 Transgenic pollen flow along NW transect.

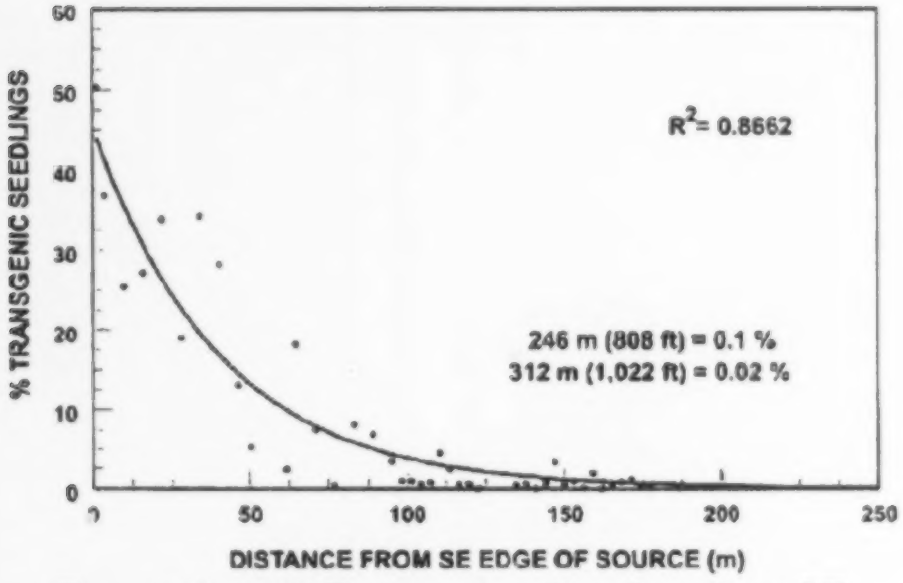

Figure 10. 1999 Transgenic pollen flow along SE transect.

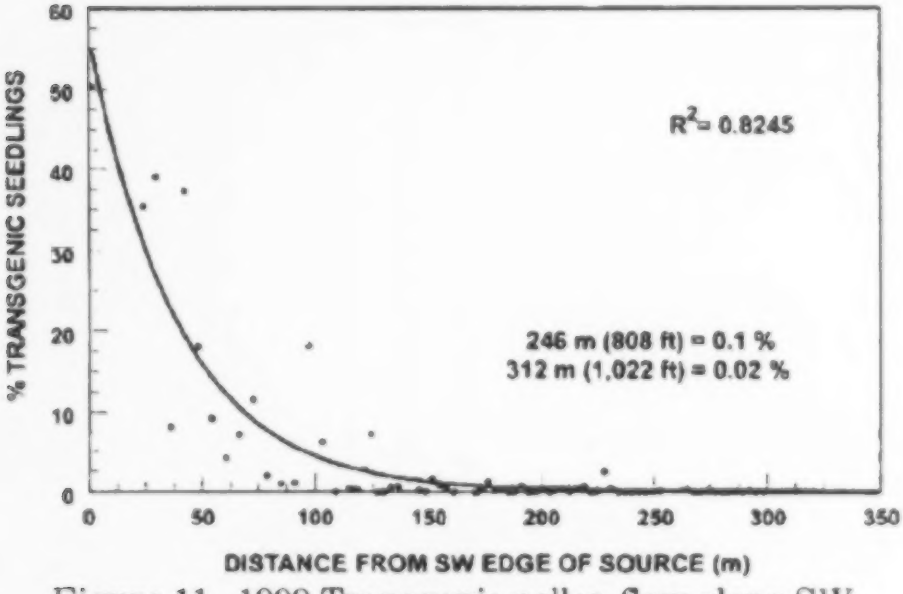

Figure 11. 1999 Transgenic pollen flow along SW transect.

The higher pollen flow in 1998 was also seen in adjacent nurseries. Seed was sampled from a nursery 638 ft (194 m) S of the transgenic nursery. Approximately two million seeds (160 g) were planted

and three applications of Finale® were applied to the seedlings. Three hundred fifty-four seedlings were found to be resistant. Five plants were sent to a lab to confirm the presence of the bar gene. Seeds are also sampled from a Penn A-1 breeder seed field 1,417 ft (432 m) SW of the transgenic nursery and a Penn A-2 field just to the SE . Two million seeds were planted of each cultivar and two to three applications of Finale® were applied to the seedlings. After the second application of herbicide, no Penn A-2 seedlings survived; however Penn A-1 had survivors. Three plants survived and vegetative material was sent to a lab to confirm the presence of the bar gene with Southern Blot analysis. The lab confirm that the surviving plants from the two nurseries did contain the bar gene.

The same two nurseries (Penn A-1 and OVN) were retested in 1999. Penn A-2 was not tested, because the nursery was destroyed during the fall 1998. Again, 160 g of seed was planted from each nursery and sprayed with 2 to 3 applications of Finale®. No seedlings survived from the Penn A-1 nursery and 459 seedlings were recovered from the OVN nursery. A sample of these possible transformants is currently being tested for the bar gene.

This not only demonstrated that pollen was viable for at least 1,400 ft (426 m), but also established successful competition with non-transgenic pollen in a field situation. The Penn A-1 nursery was 0.1 ac (0.04 ha) in size, similar to that reported by Giddings [2000] with perennial ryegrass.

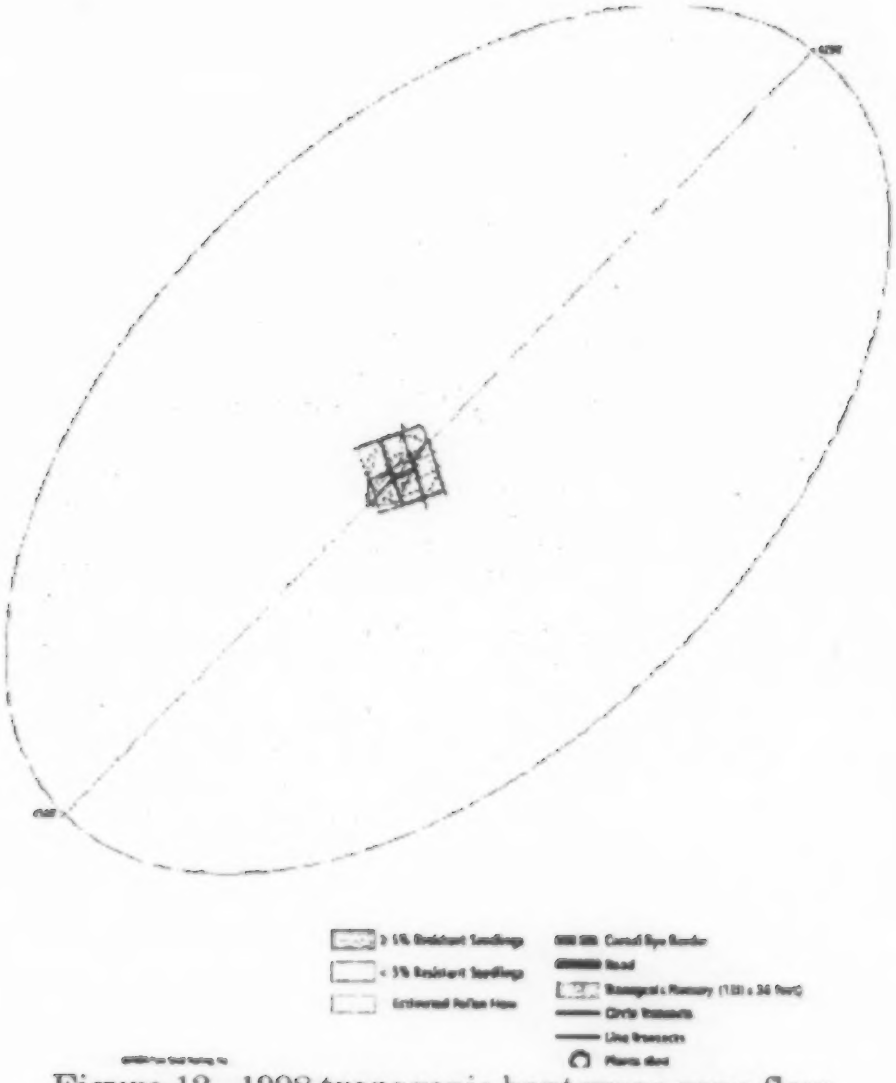

Figure 12. 1998 transgenic bentgrass gene flow.

Inter-Specific Gene Flow

The crossing experiments resulted in the introgression of the bar gene from creeping bentgrass into *A. canina*, *A. capillaris*, *A. castellana*, *A. gigantea*, *A. pallens* and *A.* sp. (eastern Oregon). The following are the results from the different species of *Agrostis* that were planted within the transgenic nursery in 1998 and 1999.

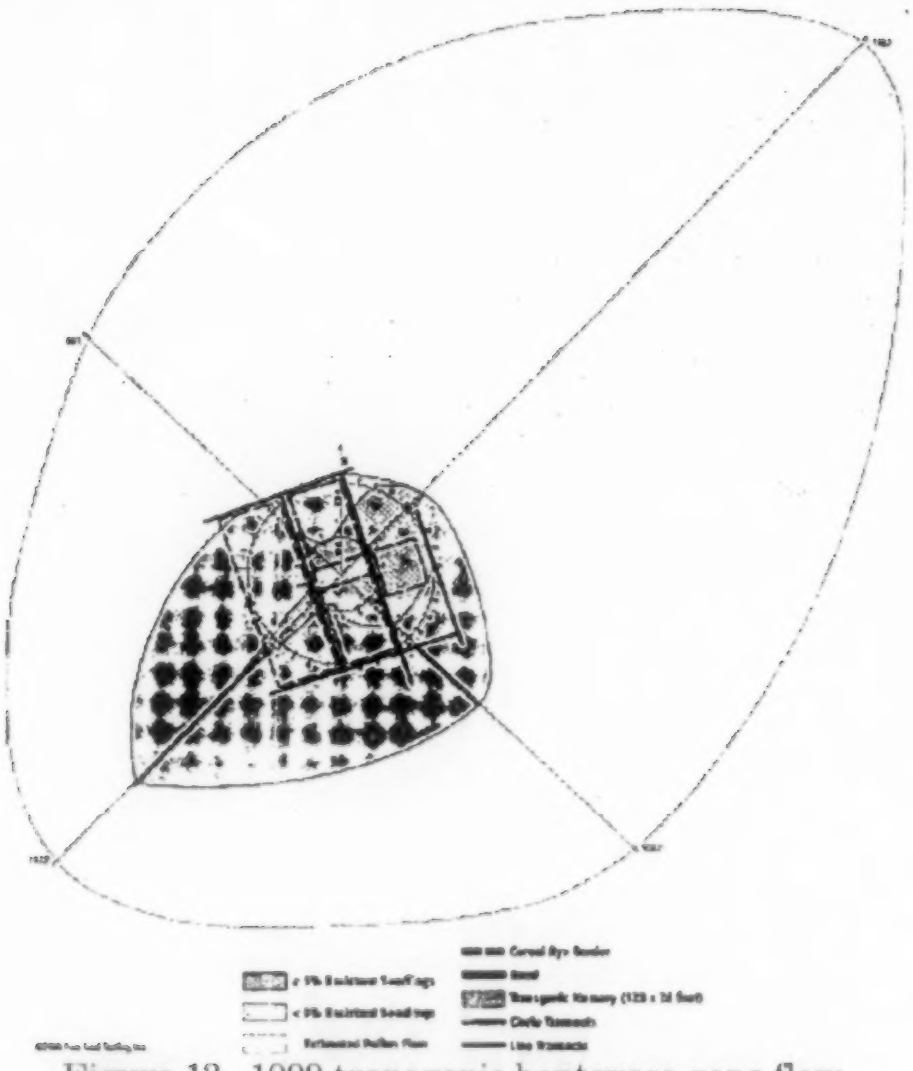

Figure 13. 1999 transgenic bentgrass gene flow.

Species	Origin or Code	Number of Survivors
A. canina	SR 7200	7
A. capillaris	9NC-20	13
A. capillaris	9NC-21	24
A. capillaris	9NC-78	0
A. castellana	New Jersey	51
A. castellana	Rhode Island	5
A. castellana	Oregon	32

Species	Origin or Code	Number of Survivors
A. curtissii	Portugal	0 (0 germination)
A. gigantea	Tennessee	1
A. gigantea	Tennessee	4
A. gigantea	Kentucky	5
A. gigantea	Kentucky	0
A. pallens	Oregon	4 (11.11 %)
A. sp.	Oregon	6 (15.8 %)

The results shoed that the transgenic gene occurred not only between species known to cross with creeping bentgrass, but also with species native to Oregon. Future research will concentrate on the stability and fertility of the interspecific hybrids and include more native species in the study.

CONCLUSIONS

The results from the this study showed: 1) the transgenic bar gene can flow to other species of *Agrostis* (i.e. interspecific gene flow); 2) intraspecific gene flow in creeping bentgrass is possible for much longer distances than traditionally theorized; 3) the transgenic bentgrass plants were fertile and stable; and 4) the cereal rye was not an effective pollen barrier.

The distance that the creeping bentgrass pollen traveled was congruent with the documented gene flow from other wind pollinated and cross-pollinated species. Giddings [2000] determined that *Lolium perenne* pollen can easily travel a kilometer. Devlin and Ellstrand [1990], using a method of paternity analysis, reported a gene flow greater than 1 % at 8000 m distance in *Agrostis capillaris* (syn = A. tenuis). Gene flow from crop to weeds or feral populations via insect

pollinators occurred up to one kilometer in: 1) radishes (*Raphanus sativus* L.) [Ellstrand et al., 1989; Klinger et al., 1991]; sunflowers (*Helianthus annuus* [Arias and Rieseberg, 1994; Whitton et al., 1997]; and squash (*Cucurbita* spp.) [Kirkpatrick and Wilson, 1988]. Thompson et al. [1999], studied gene flow in oil-seed rape (*Brassica napus*) L. at two sites. At the first site 52 sites were selected between 0 to 4000 m from the nearest crop source (no transgenic plants were being grown at this study site). At each site, male-sterile bait plants were placed for a 14 day period and airborne pollen density measured. Pollination occurred at all sited and although oilseed rape pollen was recorded at all sites, the density declined rapidly with distance from the source. In a second study with sites 100 to 900 m from a transgenic oilseed crop, all sites were pollinated by a mixture of transgenic and non-transgenic sources.

Absolute containment of transgenes is undoubtedly often impossible. Genes can not only escape via the pollen, but also through seeds that are left in fields and lost during handling. Instead of asking whether absolute containment is possible, approaches that will maximize the level of containment should be the focus. The spread transgenes through the pollen to cross-compatible populations can be prevented by: 1) male sterility which will prevent development of pollen; 2) transformation of chloroplast, which will insure that the gene is only maternally inherited; 3) growing the crop in areas where no cross compatible populations exist; and 4) at the current pace of biotechnological discoveries and development, new technology, not even thought of today, will be developed in the future that could eliminate this problem altogether. The future of

biotechnology is bright, unlimited and very exciting. This molecular revolution, like any other revolution that has occurred throughout human history, will go through growing pains. But through sound research to gather scientific data to make informed decisions and through public education of the perceived 'sci-fi' technology, the potential of this technology will be realized.

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JA-940

Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with *CP4 EPSPS* as a marker

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Edited by Peter H. Raven, Missouri Botanical Garden, St. Louis, MO, and approved August 27, 2004 (received for review July 15, 2004)

Sampling methods and results of a gene flow study are described that will be of interest to plant scientists, evolutionary biologists, ecologists, and stakeholders assessing the environmental safety of transgenic crops. This study documents gene flow on a landscape level from creeping bentgrass (*Agrostis stolonifera* L.), one of the first wind-pollinated, perennial, and highly outcrossing transgenic crops being developed for commercial use. Most of the gene flow occurred within 2 km in the direction of prevailing winds. The maximal gene flow distances observed were 21 km and 14 km in sentinel and resident plants, respectively, that

were located in primarily nonagronomic habitats. The selectable marker used in these studies was the *CP4 EPSPS* gene derived from *Agrobacterium* spp. strain CP4 that encodes 5-enol-pyruvylshikimate-3-phosphate synthase and confers resistance to glyphosate (e.g., RoundUp) herbicide. Evidence for gene flow to 75 of 138 sentinel plants of *A. stolonifera* and to 29 of 69 resident *Agrostis* plants was based on seedling progeny survival after spraying with RoundUp (Scotts, Marysville, OH) in greenhouse assays and positive TraitChek, PCR, and sequencing results. Additional studies are needed to determine whether introgression will occur and whether it will affect the ecological fitness of progeny or the structure of plant communities in which transgenic progeny may become established.

We developed sampling methods and describe results of a gene flow study that will be of interest to plant scientists, evolutionary biologists, ecologists, and stakeholders assessing the environmental safety of transgenic crops. Creeping bentgrass (*Agrostis stolonifera* L.) is one of the first wind-pollinated, perennial, and highly outcrossing transgenic crops being developed for commercial use. Unlike currently commercialized transgenic crops in the U.S., which have no synchronously flowering relatives in areas of commercial production, the cosmopolitan genus *A. stolonifera* has compatible relatives in a broad variety of habitats. The methods and results of using herbicide resistance as a selectable marker from a genetically modified (GM) crop to measure gene flow will be useful for assessing the potential for GM crops to transfer their novel genes to compatible relatives.

More data are available on gene flow from cultivated crops to other crops than from crops to resident (native, naturalized, or weedy) species (1). Typically, gene flow distances are reported on the scale of meters, much less often on the scale of kilometers. Maximum reported distance for gene flow between radish and wild radish (2) and between cultivated and wild sunflowers is 1,000 m (3); distances of 1,300 m have been reported between cultivated and wild squash (4). In an Australian study, crop-to-crop transfer distance of 3,000 m has been reported from source fields of nonGM herbicide-resistant canola to fields of herbicide-sensitive canola cultivars (5).

In this study, we present evidence that documents multiple instances at numerous locations of long-distance viable pollen movement from multiple source fields of GM creeping bentgrass. We used the *CP4 EPSPS* gene that encodes 5-enolpyruvylshikimate-3-phosphate synthase from *Agrobacterium* spp. strain CP4 as a selectable marker to track gene movement. This gene confers resistance to glyphosate (*N*-phosphono methyl-glycine), the active ingredient in RoundUp herbicide. Herbicide resistance as a result of expression of the engineered *CP4 EPSPS* gene was observed in seedling progeny of sentinel *A. stolonifera* and resident *Agrostis spp.* located at distances up to 21 km and 14 km, respectively, from the crop fields. Eight source fields totaling ≈ 162 hectares (ha) were located on an irrigated plateau above the Deschutes River in central Oregon. The fields were contained within a 4,453-ha GM bentgrass control district (http://arcweb.sos.state.or.us/rules/OARS_600/OAR_603/603_052.html; ref. 6) located ≈ 144 km east of commercial nonGM bentgrass seed production areas in

Oregon's Willamette Valley. When the source fields of GM creeping bentgrass flowered for the first time during the summer of 2003, they presented a unique opportunity to use the *CP4 EPSPS* gene as a marker to quantify viable GM pollen movement and potential gene flow to compatible resident and sentinel plants located in areas beyond the crop source fields. Results presented here use multiple lines of evidence based on assays of seedlings germinated from seed harvested from sentinel and resident plants. These assays include tests in greenhouse settings for survival after spraying with RoundUp and tests for presence and expression of the *CP4 EPSPS* marker.

A. stolonifera is a cool season, wind-pollinated perennial grass used on golf courses around the world (7). It also is of interest as a forage crop (8), for phytoremediation of heavy metals in soils (9), and for water quality improvement by biofiltration (10). The taxonomically uncertain genus *Agrostis* is estimated to include > 200 species worldwide (11, 12). In North America, 26 species of *Agrostis* are considered native, including 14 species found in Oregon (http://plants.usda.gov; ref. 13). *Argostis* is found in riparian habitats, agronomic and urban settings, mountain meadows and woodlands, coastal sand dunes, fresh and salt water marshes, ditches, pastures, grasslands, and roadsides (14, 15). The small seeds of *A. stolonifera* (up to 6 x 10^6 per pound) are readily dispersed by wind, water, and animals (14, 16). Introduced and widespread in the U.S., *A. stolonifera* is sometimes considered an economic weed, e.g., as a volunteer in grass seed or other agronomic production fields and as a colonizer of nonagricultural habitats; it has been reported as weedy in Japan, Australia, New

Zealand, Chile, Germany, Denmark, the United Kingdom, and Canada (17).

Agrostis stolonifera is generally considered to be an obligate outcrosser (18); however, self-fertility also has been reported (19). The species is most typically an allotetraploid (20, 21) and has cytotypes of higher ploidy (22). Naturally forming interspecific F_1 hybrids generally are low in fertility or sterile; in favorable habitats, some hybrids (e.g., F_1 hybrids of *A. stolonifera* and *Agrostis capillaris* L.) have been reported to out-compete both parents (23). There are few clear examples of F_2 hybrids (24) or of backcrosses of F_1 hybrids to a parental species (19). Although native or naturalized hybrids may be sterile, they can constitute a significant component of plant communities because of vegetative spread by means of stolons (25).

Field studies of hybridization between *A. stolonifera* and other species of *Agrostis* or between *A. stolonifera* and closely related *Polypogon* spp. (19, 26, 27) have produced similar findings on outcrossing ability. In a field study that included several hundred plants as sources of pollen from bentgrass engineered to be resistant to glufosinate herbicide, a gene flow distance of 298 m was reported (26). Natural hybrids of *A. stolonifera* have been reported with six other native species.: *Agrostis canina* L., *A. capillaris* L., *Agrostis castellana* Boiss. and Reuter, *Agrostis gigantea* Roth, *Agrostis mertensii* Trin., and *Agrostis vinealis* Schreb. (www.essentialbiosafety.info/docroot/articles/02-281-009.pdf; ref. 28). A computer model (29) found that pollen dispersal and gene introgression would be limited at some sites and extensive at others, depending on local wind conditions.

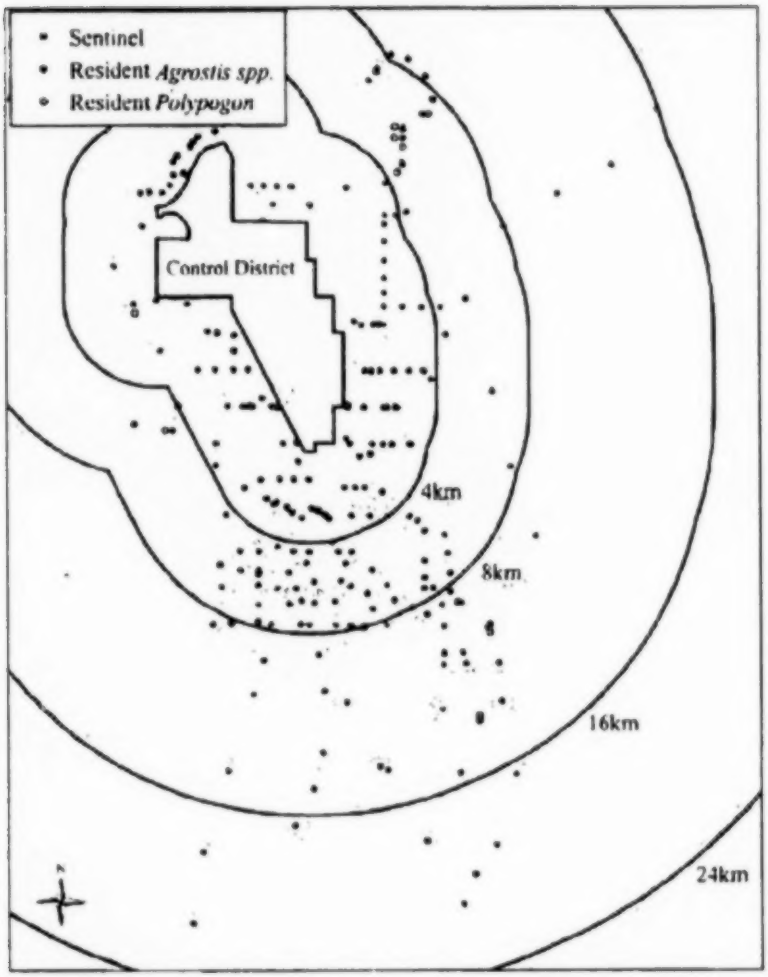


Fig. 1. Sampling design to determine gene flow from source fields within the control district to potentially compatible plants outside of the control district. A total of 178 sentinel *A. stolonifera* plants (red circles) were placed outside the control district (6) near accessible public roads spaced 1.6 km apart in the north–south direction and 0.8 km apart in the east–west direction. Given a prevailing wind of 10 km/h from the north or northwest, 76 sentinel plants were located downwind from the control district in a 9.6-km-wide by 3.2-km-deep grid with roughly 0.8-km spacing. Remaining sentinel plants were placed at 1.6-km intervals for the next 4.8 km and 3.2-km intervals for

the next 6–10 km out to a distance of 16–21 km along six transects corresponding to major highways. In addition to the sentinel plants, 69 compatible resident *Agrostis* plants (black circles) of *A. stolonifera* and *A. gigantea*, plus 10 *P. monspeliensis* (open circles) located primarily along waterways and in moist soils, were included in the study.

Materials and Methods

Sampling Design. A sampling grid (Fig. 1) was designed to determine the extent of viable GM pollen flow based on the temporary deployment of 178 compatible *A. stolonifera* sentinel plants and the monitoring of naturally occurring compatible resident plants. Critical assumptions in the sampling design included a maximal pollen viability of up to 3 h (30) and prevailing winds of 10 km/h from the north and northwest (data are from the Pacific Northwest Cooperative Agricultural Weather Network weather data archive, see www.usbr.gov/pn/agrimet/) during the expected period and hours of anthesis (e.g., mid-June to early July, from 11 a.m. to 2 p.m.) of the source GM creeping bentgrass crop fields. Thirty locations with resident plants of *A. stolonifera*, 39 locations with resident plants of *A. gigantea*, and 10 locations with resident plants of *Polypogon monspeliensis* (L.) Desf. also were included in the study. Plants of *A. stolonifera* (catalog no. 1CRBP, Seed Research of Oregon, Corvallis, OR) cultivated in a field in the Willamette Valley of western Oregon were transplanted to 23-cm diameter pots and used as sentinel plants. Before their transport to central Oregon, each of the sentinel plants tested negative for *CP4 EPSPS* by the TraitChek immunological lateral

flow test strip method (StrategicDiagnostics, Newark, DE). Each of the 69 resident Agrostis plants and the 10 *P. monspeliensis* resident plants were tested by using the TraitChek method to ensure that they were negative for the *CP4 EPSPS* protein that confers resistance to glyphosate. In mid-June, sentinel plants were deployed to field positions at times of day when anthesis from the source fields was considered unlikely (i.e., before 8 a.m. and after 6 p.m.). Additional steps taken to minimize incidental pollination of sentinel plants included bagging each plant during transit and distribution of the plants by geographic sector. Within sectors, the first plants that were put in place were those at the greatest distance from the perimeter of the control district; the last plants that were placed within a sector were those closest to the control district perimeter. In mid-July, after anthesis in the source fields had ended, panicles were bagged in the field. Bagged sentinel plants with bagged panicles and bagged panicles from resident populations were collected several weeks later. These measures allowed for *in situ* seed fill and for temporal separation with seed harvesting activities on the GM bentgrass fields. An additional precaution taken to prevent dissemination of any potentially transgenic F_1 seedling progeny from the field collections was the use of sealed boxes to transport the doubly bagged sentinel plants and the bagged resident plant panicles during their transport to greenhouses.

Greenhouse Assays. Seeds harvested from sentinel and resident plants were chilled at 5°C for 7–10 days in moist sand and grown in trays of a peat-based potting medium (Seedling Mix no. 1, OBC Northwest, Canby, OR) in the greenhouse until the two-leaf stage and then

sprayed with the field rate (2.3 L/ha) of RoundUp herbicide by using a track sprayer (model RC-500-100-EP, Mandel, Guelph, ON, Canada). Seedlings that survived the initial spraying with the field rate of RoundUp or emerged after the spray event were subjected to spraying with herbicide at twice the field rate (4.6 liters/ha) ≈ 2 weeks later. Survivors of the second cycle of herbicide spraying identified as presumptive positives were confirmed by means of the TraitChek test.

Molecular Characterization. DNeasy Plant Mini kits (Qiagen, Valencia, CA) were used to extract genomic DNA from leaves of seedling progeny derived from 130 sentinel and 45 resident plants that were both herbicide resistant and TraitChek-positive for *CP4 EPSPS*. Primers for amplification and sequencing of a 1,050-bp segment of the *A. stolonifera CP4 EPSPS* coding region were designed with PrimerSelect (DNASTAR, Madison, WI) based on *Glycine max* (L.) Merr. *CP4 EPSPS* (GenBank accession AF464188.1). Amplifications with P217F (5'-ACTATGGGCCTCGTCGGGGTCTA-3') and P218R (5'-GGCAGCCTTCGTATCGGAGAG-3') were conducted for 40 cycles of 94°C for 30 sec, 64°C for 30 sec, and 72°C for 90 sec. PCR products were purified with QIAquick Gel Extraction kits (Qiagen). Cycle-sequencing reactions used BigDye v3.1 chemistry and the standard thermal profile suggested by the manufacturer (Applied Biosystems). Labeled fragments were purified with CleanSeq kits (AgenCourt Bioscience, Beverly, MA). Sequence data were collected on an Prism 3100 Genetic Analyzer (Applied Biosystems). Sequences were then compared

with matching GenBank accessions by using BLASTN searches (31).

Statistical Analyses. The percent positive seedling progeny was calculated as the number of seedlings that survived two sprays with RoundUp and had positive TraitChek tests for the *CP4 EPSPS* gene divided by the total estimated number of seedlings germinated in the greenhouse. A maximum likelihood estimation was used to fit the two-parameter γ distribution (32), $f(\chi) = \chi^{(\alpha - 1)} \exp(-\chi/\beta)/(\Gamma(\alpha)\beta^{\alpha})$, where α and β are the model parameters and $\Gamma(\cdot)$ is a complete γ function, to the observed distances from the control district perimeter at which positive seedling progeny were found. The adequacy of the γ distribution was tested by using the one-sample Kolmogorov–Smirnov test (33, 34). The two-sample Kolmogorov–Smirnov test (35) was used to compare the probability distributions of the positive seedling progeny of sentinel and resident plants. Nonparametric kernel smoothing (36) was applied to percent positive seedling progeny to generate spatial maps of gene flow transfer for sentinel and resident plants separately. The estimation and hypothesis testing of the γ distributions were performed by using S-PLUS v6.01 (Mathsoft, Cambridge, MA). Kernel smoothing and spatial maps were undertaken by using ARCMAP v8.3 and the ARCGIS extension 8.3 spatial analyst (Environmental Systems Research Institute, Redlands, CA).

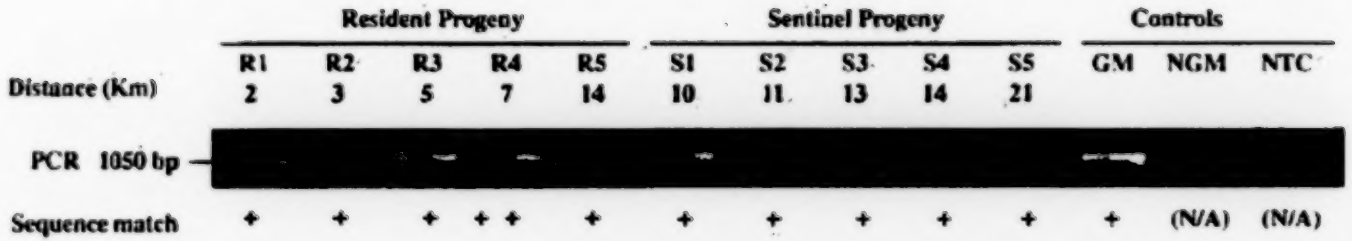


Fig. 2. Molecular confirmation of the presence of the engineered *CP4 EPSPS* herbicide-resistance gene. The presence of the *CP4 EPSPS* gene as verified in a subsample of TraitChek-positive progeny from resident (R1–R5) and sentinel (S1–S5) plants located at various distances from the control district perimeter. All PCR products had the same size and DNA sequence as that amplified from the GM-positive control (*A. stolonifera*, designated event ASR368). BLASTN searches (31) revealed that the DNA sequences also matched GenBank accessions AF464188.1, *Glycine max CP4 EPSPS* (score=1,271, E=0.0), and AY125353.1, a synthetic *CP4 EPSPS* construct. Negative controls included DNA from nonGM (NGM) *A. stolonifera*, variant Penncross, and a nontemplate control (NTC). +, positive sequence matches; N/A, not applicable.

Results

Gene Flow to Sentinel and Resident Agrostis. Molecular analyses by PCR (see Fig. 2) and by sequencing (sequence data not shown) confirmed the presence of the *CP4 EPSPS* marker in seedling progeny that had survived two cycles of spraying with RoundUp herbicide. The sequence matched that of GenBank accession AF464188.1 for a *CP4 EPSPS* construct in glyphosate resistant soybean (*G. max*). The highest relative frequencies of pollen-mediated gene flow to *A. stolonifera* sentinel and *A. stolonifera* and *A. gigantea* resident plants were observed within 2 km of the control district perimeter. Maximal distances at which gene flow was observed in sentinel and resident *A. stolonifera* and resident *A. gigantea* plants were ≈ 21 km, 8 km, and 14 km, respectively. Viable pollen dissemination distances for sentinel plants may be biased low because this distance of 21 km represented the limit of the sampling design (Fig. 1). An additional source of bias is that distances from source fields to the control district perimeter were unknown. Based on the one-sample Kolmogorov–Smirnov goodness-of-fit test, the empirical distribution of minimum distances of the 75 positive sentinel *A. stolonifera* plant locations (Fig. 3*A*) was adequately described by a γ distribution with $\alpha = 0.93$ and $\beta = 4.1$ ($P = 0.67$); that of 16 positive resident *A. stolonifera* plant locations (Fig. 3*B*) was adequately described by a γ distribution with $\alpha = 0.74$ and $\beta = 4.0$ ($P = 0.77$); and that of 13 positive resident *A. gigantea* plant locations (Fig. 3*C*) was adequately described by a γ distribution with $\alpha = 0.74$ and $\beta = 2.8$ ($P = 0.42$). The mean ($\alpha\beta$) and variance ($\alpha\beta^2$) of a γ distribution decrease monotonically with respect to α and β. Consequently,

higher α and β values indicate density distributions of viable pollen that hybridized with sentinel or resident plants that were spread farther from source fields. The γ distributions for sentinel and resident *A. stolonifera* locations were not significantly different at the 0.05 level based on the two-sample Kolmogorov–Smirnov test (P = 0.63) but were significantly different from that for resident *A. gigantea* locations (P = 0.031 and 0.047, respectively). The mean distance from the perimeter of the control district ranged from 2.1 km for resident *A. gigantea* plant locations to 3.8 km for sentinel plant locations.

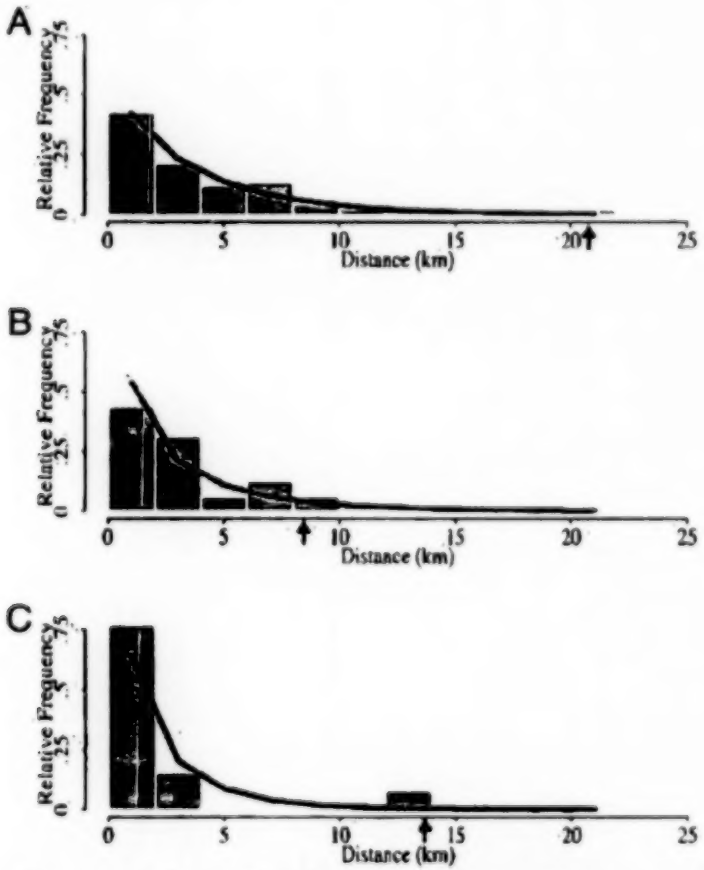
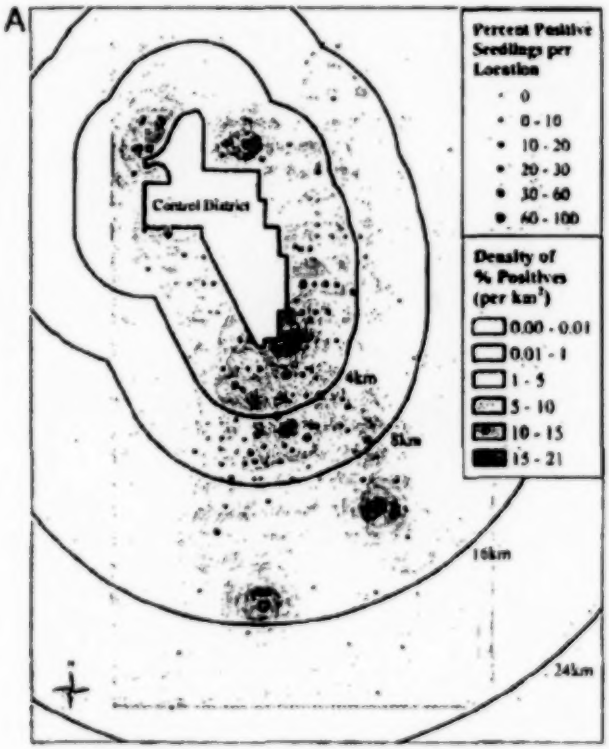


Fig. 3. Skewed distribution of GM bentgrass pollen-mediated gene flow to sentinel and resident plants in

2003. Based on the presence and expression of the *CP4 EPSPS* gene for herbicide resistance, relative frequencies of gene flow among sentinel and resident plant seedling progeny were highest within the first 2 km from the perimeter of the control district and decreased with distance. Arrows depict maximal gene flow distances that were observed. *A*, *B*, and *C* represent locations of sentinel *A. stolonifera*, resident *A. stolonifera*, and resident *A. gigantea* plants, respectively.



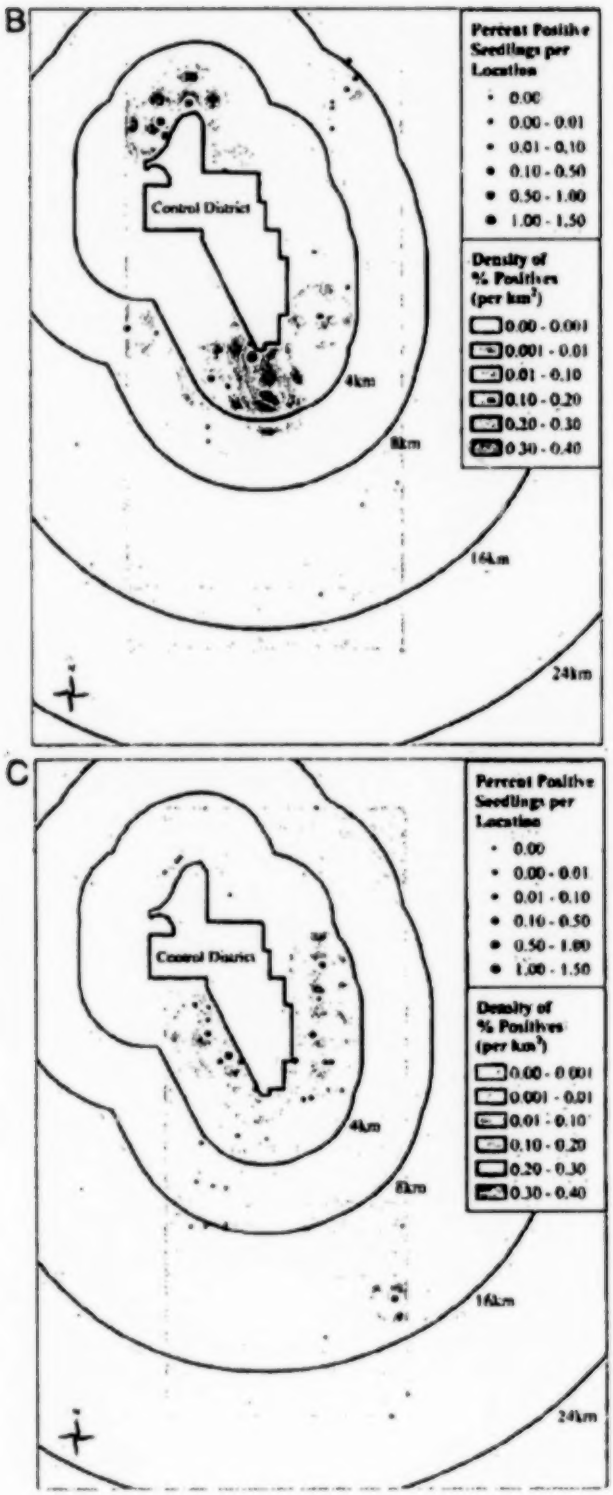

B
Percent Positive Seedlings per Location
0.00
0.00 - 0.01
0.01 - 0.10
0.10 - 0.50
0.50 - 1.00
1.00 - 1.50
Density of % Positives (per km²)
0.00 - 0.001
0.001 - 0.01
0.01 - 0.10
0.10 - 0.20
0.20 - 0.30
0.30 - 0.40
Control District
4km
8km
16km
24km
C
Percent Positive Seedlings per Location
0.00
0.00 - 0.01
0.01 - 0.10
0.10 - 0.50
0.50 - 1.00
1.00 - 1.50
Density of % Positives (per km²)
0.00 - 0.001
0.001 - 0.01
0.01 - 0.10
0.10 - 0.20
0.20 - 0.30
0.30 - 0.40
Control District
4km
8km
16km
24km

Fig. 4. Prevalence of gene flow based on percent positive seedling progeny of sentinel and resident plants at various distances from the control district perimeter. Kernel smoothing (31) was applied to percent positive seedling progeny (filled circles) of sentinel *A. stolonifera* plants (*A*), resident *A. stolonifera* plants (*B*) and resident *A. gigantea* plants (*C*) to generate spatial maps of the density of percent positives. Empty circles indicate locations where no positive seedling progeny were found. The highest densities of percent positive seedling progeny of sentinel and resident *A. stolonifera* plants occurred southeast and/or due south of the perimeter of the control district, in the direction of the prevailing winds.

Table 1. Prevalence and incidence of *CP4 EPSPS*-positive plants and seedling progeny

Species	Plants with positive seedling progeny, %*	No. tested†	No. postive seedling progeny (%)
Sentinel *A. stolonifera*	54 (75/138)	32,000	625 (2.00)
Resident *A. stolonifera*	53 (16/30)	565,000	157 (0.03)
Resident *A. gigantea*	33 (13/39)	397,000	159 (0.04)
Resident *P. monspeliensis*	0 (0/10)	190,000	0 (0.00)

*Values in parentheses represent the ratio of plants with postive seedling progeny to the total number of plants.

' Number of seedling progeny tested in greenhouse.

Spatial Patterns of Gene Flow. For both sentinel and resident *A. stolonifera* plants, the greatest spatial density of percent positive seedlings was found southeast and south of the control district in the direction of prevailing winds (Fig. 4 *A* and *B*). Positive seedlings derived from resident *A. gigantea* were found primarily east and west of the southern portion of the control district (Fig. 4C). In addition, some CP4 EPSPS-positive *A. stolonifera* seedling progeny were obtained from seeds harvested from plants near and below the northwest section of the control district perimeter (Fig. 4 *A* and *B*). This finding may be due to localized temperature gradients and wind conditions near the rim of the Deschutes River canyon, which brought viable pollen down to the canyon floor. In comparison, the percentage of positive sentinel plants was about an order of magnitude higher than that for resident plants.

Resident *Agrostis* typically were found in moist soils, e.g., riparian areas and along irrigation or drainage ditches. Most of the *A. stolonifera* resident plants with positive seedling progeny were located in sagebrush steppe or other nonagronomic land use areas (50% and 25%, respectively), whereas the majority (78%) of positive *A. gigantea* plants were located in agronomic production areas. Forty of 178 sentinel plants were lost to various causes, e.g., transplant shock and grazing. As shown in Table 1, hundreds of CP4 EPSPS-positive seedling progeny were found

among viable *A. stolonifera* sentinel and resident plants and *A. gigantea* residents.

Discussion

Our multiple lines of evidence from greenhouse and laboratory tests document movement of viable GM creeping bentgrass pollen on a landscape level that encompassed ≈ 310 km^2. The gene flow evidence presented here contrasts quantitatively with previous studies with *A. stolonifera* (19, 26, 27) with significantly higher numbers of occurrences and maximally observed linear distances. The higher number of observed occurrences may reflect greatertotal acreage of source fields in this study (162 ha) as compared with much smaller experimental field plots of previously reported studies with *Agrostis* in which only several hundreds of plants served as pollen donors. The long period of flowering (estimated at 4–5 weeks rather than a more typical flowering period of 2–3 weeks for creeping bentgrass in the Willamette Valley), may have been due to asynchronous flowering of GM crop source fields. Potential causes of floral asynchrony include differences in cultivars, soil characteristics, and microclimates among source fields. The long gene flow guided by historic information on prevailing winds (www.usbr.gov/pn/agrimet) as well as a 3-h window of assumed pollen viability (30). Our landscape level sampling design was distinct from "wagon-wheel" designs typically used for gene flow determinations in agronomic settings; i e., with regard to its geographic scale of several hundreds of kilometers-squared rather than linear meters, in the broad variety of nonagronomic as well as agronomic habitats that it encompassed, and in the use of both sentinel and resident plants.

Lower frequencies of gene flow observed in resident *Agrostis* as compared with sentinel plants are likely primarily due to initiation of flowering of resident plants 2–3 weeks later than crop source fields. Pollen competition i.e., pollen loads in the vicinity of patches of resident plants were higher than around individual sentinel plants, may also have reduced the relative availability of stigma sites for GM pollen in resident plants. Diverse factors (37) may have resulted in our lack of observations of gene flow to *P. monspeliensis* resident plants; two reasons we consider most likely are flowering of *P. monspeliensis* residents 2–3 weeks later than the bentgrass fields and their generally upwind locations.

Our results clearly document pollen movement and gene flow from large source populations of GM creeping bentgrass into much smaller numbers of resident Agrostis plants and individual sentinel plants of *A. stolonifera*. Conceivably, gene flow to resident plants from small-scale field trials of GM creeping bentgrass initiated within the control district before 2003 (www.agcomm.ads.orst.edu/agcomwebfile/edmat/html/sr/sr1046. 9htm; ref. 38), e.g., by wind-dispersed pollen or seeds, may have contributed to the observations we report here. However, all tests done to date on leaf and panicle tissue samples of resident plants that produced *CP4 EPSPS*-positive seedling progeny in our greenhouse assays have proven negative for the marker. Efforts will continue over the next few years to identify potential establishment and recruitment of resident Agrostis that express the *CP4 EPSPS* marker. More detailed molecular analyses of positive seedlings and of maternal or paternal crop or resident plant parents are planned to distinguish

hybridization events between GM crop and resident plants from GM crop seed dispersal. Multiyear sampling to monitor potential introgression of the *CP4 EPSPS* marker into resident populations and for potential effects on plant community structure and the ecological fitness of progeny also is planned.

In competitor–stress tolerator–ruderal characterization of plant functional types (14, 39), *A. stolonifera* is considered to have both competitive and ruderal features; thus, its invasive root and stolon growth can contribute to weediness, and new plants can be established either by seeds or by dispersal of stolon pieces (14, 16, 40, 41). The particular engineered trait for herbicide resistance (*CP4 EPSPS*) that we used as a selectable marker would not be anticipated *per se* to confer a selective advantage in the absence of herbicide selective pressure. However, in areas where weed control or restoration efforts are being practiced, hybrid *Agrostis* progeny resistant to glyphosate herbicide might be expected to have a selective advantage. Further studies should continue over the next few years within resident plant populations to monitor for introgression, spread or extinction of the engineered *CP4 EPSPS* gene, and for potential effects on ecological fitness of progeny and plant community structure in various, largely nonagronomic habitats.

Biological confinement strategies (e.g., male sterility, gene insertion into organelles or into targeted chromosomes or chromosome sites) are of interest to try to restrict gene flow; however, recent reports (42, 43) suggest that gene leakiness may make fully effective, long-term containment of transgenes unlikely. Studies, such as the one reported here, that use both sentinel- and resident-compatible plants in an

appropriately large sampling design that includes nonagronomic and agronomic habitats may be useful to quantify potential rates of gene exchange between GM or conventional crops and nonagricultural resident plants when conducting assessments of ecological risks (37) and evaluating potential mitigation technologies (43). Similar approaches could be used to develop sampling designs to test for potential long-distance wind dispersal of GM seeds. Our methods and findings contribute significantly to the ongoing discussion about potential risks of gene flow from GM crops and thus are anticipated to be of interest to plant scientists, evolutionary biologists, ecologists, policy makers, and regulators.

We thank Scotts and Monsanto (St. Louis) for providing leaf tissue samples and molecular information; Oregon State University, especially the staff at the Central Oregon Agricultural Experiment Center, for facilitating our studies in central Oregon; Bruce MacBryde (U.S. Department of Agriculture, Washington, DC) for a comprehensive review of *Agrostis* literature; Joseph Wipff (Pure Seed Research, •••) for helpful discussions on *Agrostis* biology, and Leah Brilman (Seed Research of Oregon) for providing *A. stolonifera* for use as sentinel plants. This research was funded by the U.S. Environmental Protection Agency, Office of Research and Development, National Health and Environmental Effects Research Laboratory. This document has been cleared by the U.S. Environmental Protection Agency for publication.

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JA-965

Pollen-Mediated Movement of Herbicide Resistance Between Commercial Canola Fields

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There is considerable public and scientific debate for and against genetically modified (GM) crops. One of the first GM crops, *Brassica* napus (oilseed rape or canola) is now widely grown in North America, with proposed commercial release into Australia and Europe. Among concerns of opponents to these crops are claims that pollen movement will cause unacceptable levels of gene flow from GM to non-GM crops or to related weedy species, resulting in genetic pollution of the environment. Therefore, quantifying pollen-mediated gene flow is vital for assessing the environmental impact of GM crops. This study quantifies at a landscape level the gene flow that occurs from herbicide-resistant canola crops to nearby crops not containing herbicide resistance genes.

Data on pollen dispersal has mostly been obtained from small-scale field trials of limited sample size (*1–5*). Canadian experiments with GM canola found less than

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0.03% pollination at 30 m into conventional varieties (*6*). However, Hall *et al.* (*7*) suggested GM canola pollen moved over greater distances. Therefore, we examined pollen movement between herbicide-resistant canola and conventional varieties on a commercial scale, testing over 48 million individual plants. This was possible because canola resistant to acetolactate synthase (ALS)–inhibiting herbicides was grown commercially in Australia for the first time in 2000. These first commercial fields served as the herbicide resistance gene source in an uncontaminated environment. This variety has a two-gene system—one herbicide resistance gene on each genome—and is homozygous for both genes. Therefore, any crosses to a conventional variety will contain one copy of each gene.

To assess gene flow, seeds were collected from 63 conventional canola fields growing near herbicide-resistant fields in New South Wales, Victoria, and South Australia. These three states represent over half of the canolagrowing area in Australia as well as a wide and diverse range of environments. Source and sink fields were of similar sizes, ranging from 25 to 100 ha. At crop maturity, 10 stratified samples totaling at least 100,000 seeds were taken from each of three locations in each field of conventional canola. These were parallel to the source field and taken at the edge nearest to the source field, the middle, and the edge furthest from the source field. Collected seed samples (500 g) were planted as separate plots, in an irrigated field, along with two resistant and two susceptible canola controls. To determine whether pollen-mediated gene flow from source to sink fields had occurred, we screened the seedlings with a lethal

discriminating dose of the ALS-inhibiting herbicide chlorsulfuron, and any survivors were further confirmed by a repeat treatment 14 days later.

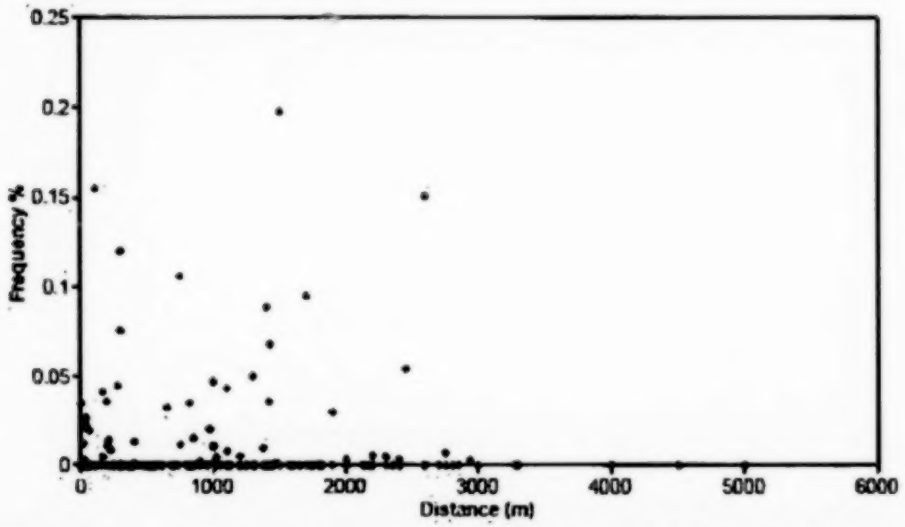

Fig. 1. Percentage of ALS herbicide-resistant individuals in seed from nonresistant varieties in relation to distance from the source field. Three individual samples were collected per field, with 190 individual collection locations.

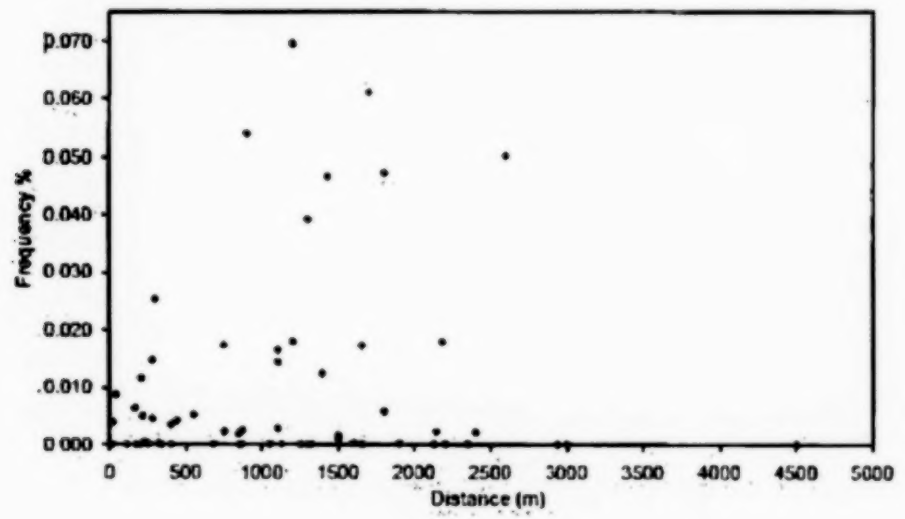

Fig. 2. Percentage of ALS herbicide-resistant individuals in seed from nonresistant varieties in relation to distance from the source field. Samples pooled per field, with 63 fields sampled.

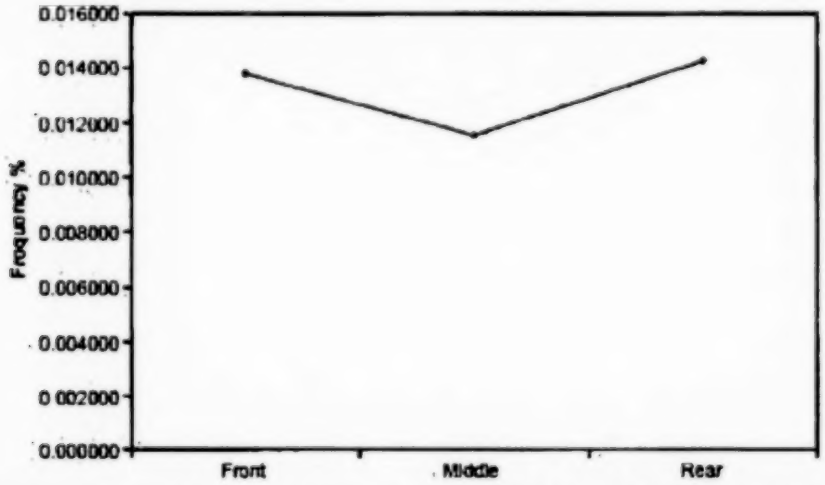

Fig. 3. Percentage of ALS herbicide-resistant individuals by location within field (edge closest to source, middle, and rear edge) of sample collection. Data are only for those fields with the nearest edge within 100 m of the pollen source.

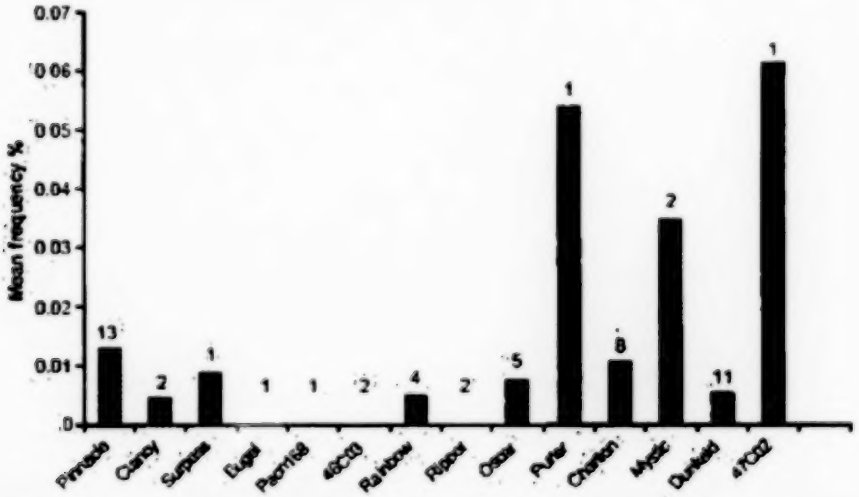

Fig. 4. Percentage of ALS herbicide-resistant individuals in sink fields by variety. The number of

fields screened (numeral above each bar), percentage of resistance recorded, and variety are given.

Only 30% of samples screened revealed ALS herbicide-resistant individuals; the remainder had no detectable resistance. Resistance frequencies varied up to a maximum of 0.197% (Fig. 1). When individual samples were 0.040 pooled within fields, resistance was evident in 63% of these fields, although only a few had more than 0.03% resistance (Fig. 2). The results show that, in most cases, gene flow via pollen movement occurs between canola fields. However, even adjacent commercial canola fields in Australia will have much less than 1% gene flow. Resistance was not detected in fields more than 3 km from the source, although the number of fields sampled was not large (Fig. 2).

Previous researchers (*2*, *4*, *6*, *8*) have recognized that herbicide resistance is a powerful genetic marker, providing that other sources of resistance are excluded. For ALS herbicide resistance, it is acknowledged that natural but low frequencies of resistance have been reported (*9*). This level was measured at 10^{-6} in the Australian variety Karoo in previous experiments conducted by our research group (data not shown). Other sources of contamination must be small, because the highest frequency of resistance detected on a field basis was 0.07% and because no resistance was detected in 23 fields, despite the examination of over 700,000 seedlings.

Edge effects have been consistently observed in all previous pollen movement work (*4*, *6*, *10*, *11*), with cross-pollination occurring at higher frequencies closer to the source field. However, comparison of samples within fields did not demonstrate a consistent edge effect. That is, samples from the leading edge of fields

did not always have a higher level of resistance. In fields where the front edge was less than 100 m from the herbicide-resistant field, similar frequencies of resistance were found at all three collection points within the field (Fig. 3). Overall, some fields did show a decline in resistant individuals with distance, but the majority of fields, particularly those further from the source field, were more variable. The edge effect observed in this large-scale landscape study was uniformly low and did not appear to unduly influence pollination events.

This study is unique for several reasons: it was conducted with large commercial canola fields, used large sample sizes, and was conducted over one-third of Australia, which covers a range of environments. Another unique aspect of this investigation is that the pollen sources were large (25- to 100-hectare fields), unlike other studies where relatively small sources have been used. The use of large commercial fields rather than small, artificial pollen sources has revealed that there is a small amount of pollen-mediated gene movement up to 3 km from a source field. We did not observe a leptokurtic or exponential decline, as found in many small-scale studies (*1*, *5*, *10*, *12*). Instead, a more variable distribution with isolated pollination events was detected. The multiple pollinating agents (wind and insects) of canola and the large size of the source may contribute to the randomness of long-distance pollination events.

Varietal differences among canola sink fields were observed (Fig. 4), but no consistent effect of wind direction on pollen-mediated gene flow was detected (data not shown). The variety of canola may be a contributing factor in random pollination events at

distance. Pollination has been shown to be affected by crop variety (*12*). Varieties have differences in flowering period, which will affect pollination events over such a large scale. Another explanation for these seemingly random events may also be related to insect behavior. Roaming insects may target single plants flowering early or late in a field, resulting in sporadic pollen movement. However, insects are more likely to remain in a single field if sufficient resources (e.g., flowers) are readily available (*13*).

Gene transfer is a complex process and is dependent on many factors (*14–16*), including environmental conditions, plant variety, insect behavior, and plant density. These observations, coupled with our data on long-distance pollen movement, indicate that laboratory and small-scale experiments may not necessarily predict pollination under commercial conditions. This study demonstrates that cross-pollination between commercial canola fields occurs at low frequencies but to considerable distance.

References and Notes

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17. We would like to thank P. Salisbury, S. Fisher, and W. Burton (Agriculture Victoria); S. Sutherland, P. Parker, P. Mathews, and G. Condon (New South Wales Department of Agriculture); and D. Lorraine-Colwill, B. Mack, and S. Garvie (Adelaide University) for the collection of the seed samples. We would also like to thank all the farmers who

participated in this study. WAHRI is an initiative of the Grains Research & Development Corporation.

8 March 2002; accepted 13 May 2002

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C06-01075 CRB
Plaintiffs,	) DECLARATION OF CHARLES
vs.	) BENBROOK IN SUPPORT OF
MIKE JOHANNS, et al.	) PLAINTIFFS PERMANENT
Defendants,	) INJUNCTION
and	) Date: April 27, 2007
	) Time: 11:00 a.m.
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	)

I, Charles M. Benbrook, do hereby declare as follows:

1. I have personal knowledge of the technology and issues at the heart of this litigation and could competently testify if called as a witness.

2. I reside at 90063 Troy Road, Enterprise, Oregon 97828 and am not a party to this lawsuit, nor do I have any personal or professional relationship to any party involved with the litigation.

3. Currently, I am Chief Scientist of The Organic Center, a nonprofit research organization. I am also president of Benbrook Consulting Services, a consulting business that provides services to domestic and international clients in the areas of agricultural technology, policy, food safety, and environmental quality. Areas of work include biotechnology, pesticide use, risk and regulation, and adoption and cost-benefits of Integrated Pest Management strategies.

4. Prior to my consulting business and from 1984-1990 I served as Executive Director of the Board of Agriculture of the National Research Council/National Academy of Sciences (NRC/NAS). During my tenure at the Academy, I oversaw and carried out a number of NRC/NAS studies covering a range of topics associated with the use of genetic engineering to produce novel plant varieties, and the impacts of genetically engineered plants and animals. These included assessment of molecular biology research priorities; preservation, sharing, and use of plant genetic resources; environmental fate of novel pest management technologies; the unique risks faced by infants and children from pesticides exposure; the modernization of U.S. pesticide regulatory law; pesticide use and resistance; and, applications of genetic engineering to crop varietal improvement.

5. Prior to NRC, I worked as staff director for Subcommittee on Department Operations, Research and Foreign Agriculture, Committee of Agriculture, U.S. House of Representatives from 1980-1984, and as Agricultural Policy Analyst for the Council on Environmental Quality, Executive Office of the President in 1979-1980.

6. I hold a BA in Economics from Harvard University and MA and PhD in Agricultural Economics from the University of Wisconsin. I have authored numerous peer-reviewed articles on the subject of pest management systems, technology, and risks. My full *curriculum vitae* is attached herein as Exhibit A.

7. As part of my consulting work, I have authored several reports on Roundup Ready crops, with a special focus on the impacts on herbicide use, and environmental and economic consequences. I completed a report entitled *Genetically Engineered Crops and Pesticide Use in the United State: The First Nine Years* in 2004, the first comprehensive assessment of the impacts of GE crops on pesticide use carried out by an analyst independent of the government and biotechnology/pesticide industry. A true and correct copy of this study is attached as Exhibit B.

8. In all my work on the impacts of genetically engineered (GE) crops on pesticide use, I rely on publicly available data from the USDA's National Agricultural Statistic Service (NASS).

10. From 1983 to 1992 I rented and operated a 265-acre farm near Poolesville, Maryland. I planted approximately 90 acres of alfalfa in 1984 or 1985, and harvested and marketed the crop from this planting each year until I left the farm in 1992. I carried out all aspects of planting, managing, and harvesting the crop. Three to four cuttings were done annually; total production varied between three and five tons per acre. Prior to living in Maryland, I ran a large farm in British Columbia, Canada from 1974-1978, where hay was the principal cash crop. We harvested approximately 400 acres of hay annually on the B.C.

farm. I have followed the agronomic practices, impacts, and economics of alfalfa production since the early 1980s.

11. I have reviewed the "Direct Testimony of Timothy J. Nantell Regarding Permanent Relief" and have been asked by counsel for plaintiffs to assess the assumptions, analytical methods, and data used by Professor Nantell. In addition, I have been asked to project the economic impacts of Roundup Ready (RR) alfalfa on the organic food industry, if commercial plantings were to again be allowed.

12. Professor Nantell projects that the injunction will impose aggregate impacts of $225,000,000, assuming the injunction is lifted in time for commercial plantings to begin in the fall of 2009. Professor Nantell attributes the majority of these costs—$205 million, or 91%—to impacts on forage growers, i.e. lost net farm income.

13. A "Report of Timothy J. Nantell" is identified as Exhibit A and is attached to the Professor's Direct Testimony. This exhibit sets forth the basis of the impact estimate noted above. Unless otherwise noted, all comments herein address provisions in the Nantell Report.

14. Point 5 (page 2) in the Nantell Report sets forth critical assumptions underlying his estimates. These assumptions include that the injunction will be lifted in 2009; that growers with RR alfalfa already planted may harvest and utilize the crop; and, that seed producers under contract to produce RR seed may harvest and stockpile the seed.

15. These assumptions, and data on alfalfa production costs and returns, were incorporated by Professor Nantell into a cash-flow model typical of

those used by farmers to estimate the profitability of a given business enterprise, in this case, the planting of a field to RR alfalfa. Impacts are also projected at each stage of the supply chain, beginning with impacts on seed growers and Forage Genetics, Inc. (FGI), and then including impacts on other seed companies and dealers, and finally alfalfa farmers.

16. Point 13 in the Nantell Report states the assumption that RR alfalfa seed growers already contracted to produce RR seed for FGI, from already planted/existing stands, will harvest seed and sell it to FGI under the terms of the contract. Such a course of action makes economic sense only if one assumes that the injunction will be lifted in time for plantings to resume in 2009. This assumption is questionable on four grounds.

First, it is clearly presumptuous to assume the injunction will be lifted and that this litigation will be concluded in favor of FGI. It is equally presumptuous that the USDA will complete an Environmental Impact Statement ("EIS") by 2009, and that the EIS will conclude that Roundup Ready alfalfa may be deregulated without any harm to the environment.

Second, there is growing concern among alfalfa industry leaders regarding the loss of markets if RR alfalfa is widely planted, especially in California, which is the source of substantial alfalfa hay exports to markets in Asia that will not allow GE food or animal feeds to enter their markets.

Third, the high cost of the seed, coupled with some evidence of production problems and poor control of certain weeds (several such problems are outlined in the University of California report posted at http://anrcatalog.ucdavis.edu/pdf/8153.pdf), renders the

economics of RR alfalfa largely a wash for farmers, much like the economics governing other GE, herbicide-tolerant crops.

Fourth, lingering debate over this technology, and the current litigation, has raised public and grower awareness of the probable negative environmental consequences of RR alfalfa, especially gene outflow to non-GE varieties of alfalfa and the emergence of weeds resistant to glyphosate (including RR alfalfa, which will become a weed when it grows in areas outside farmer-fields where vegetation must be managed). This awareness may trigger more careful observation of RR alfalfa in the field, and new research, generating information that will lead the USDA to change its initial judgment regarding the technology. Even if USDA completes an EIS, and again deregulates RR alfalfa for commercial use, market opposition may build fast enough to dramatically reduce the acreage ultimately planted.

17. RR alfalfa seed growers under contract to FGI could instead be directed by FGI to harvest high quality hay from their plantings, which would maximize the non-seed income from the plantings and prevent any substantial risk of gene flow (since the plants would be cut prior to flowering; alfalfa protein content is highest just prior to flowering). FGI could then pay their contract growers the relatively modest difference between projected seed income and income from high-quality hay sales.

18. Professor Nantell assumes in his model that the RR alfalfa seed that is harvested in 2007 and 2008 will be needed to meet growing demand in 2009. This assumption is flawed because there is no way of knowing how rapidly demand will grow, or whether it

will grow at all, given the marginal economics of the technology for the average grower.

19. In point 15, Professor Nantell correctly states that the economic impacts of the injunction on growers must take into account the "mitigating products" the farmers would decide to produce in the absence of access to RR alfalfa seed. He states categorically that:

> "The mitigating products are less efficient, more costly, consume more of the growers' time and are harder on the growers' land than is the case with RRA."

There is no way Professor Nantell, or anyone, can so assuredly and comprehensively predict future farm crop costs and returns. Just two years ago, corn farmers struggled to cover cash costs, and in fact depended on government payments to cover about one-third of their average costs of production. Rapid growth in the ethanol industry has lead corn prices to almost double from just two years ago. Essentially all cropland suitable for producing alfalfa is also suitable to produce corn. Indeed, corn and alfalfa are grown in rotation with each other across the country. Corn prices over $4.00 per bushel will lure to corn production considerable acreage previously planted to alfalfa. The USDA is projecting a huge increase in corn acres in 2007, with likely over a million acres of new corn coming at the expense of alfalfa acreage—clear evidence that Professor Nantell failed to anticipate at least one important "mitigating product."

The statement that the "mitigating products are less efficient" is so vague it is meaningless. Efficient with respect to what—cash costs, energy, labor, water use? Measured how? Based on what data? The Nantell report provides no details or explanation.

The statement that mitigating products would be "more costly" is highly doubtful, given that RR alfalfa is by far the most costly variety of alfalfa to plant. "Consume more of the grower's time" is equally questionable, given that the agronomic tasks associated with growing conventional and RR alfalfa are nearly identical. There clearly are several crop options other than RR alfalfa that would take less grower time and management attention.

The assertion that mitigating products would have a greater impact on the environment is also doubtful for several reasons:

- RR alfalfa depends upon applications of an herbicide known to adversely impact soil microbial communities, whereas most of conventional alfalfa is grown without herbicides;
- Applications of glyphosate on leguminous RR plants (like alfalfa) impair the natural ability of the plant to affix nitrogen, increasing the farmer's future dependence on purchased forms of nitrogen (all with a suite of adverse environmental impacts);
- RR plants often prove more susceptible to common soil pathogens, increasing the risk of diseases losses and/or the need for fungicide applications in subsequent rotational crops; and
- The spread of RR resistance weeds and RR alfalfa to non-crop areas will increase reliance on higher risks herbicides and weed management systems and increase weed management costs for a wide range of public and private entities.

- Removal of stands of RR plants requires the use of more toxic herbicides because Roundup is ineffective to remove RR stands of alfalfa.

Already, University of California scientists conducting field trials with Roundup Ready alfalfa have noted shifts in the composition of weed species toward those harder to control with Roundup. In an April 5, 2007 "Spotlight Story" on a University of California agricultural extension website (http://ucanr.org/spotlight/gmoalfalfa.shtml), U.C. cooperative extension farm advisor Mick Canevari states that they have already seen "...a 'weed shift' in his experimental plots where Roundup Ready alfalfa has been grown for three years." Canevari goes on to explain:

> "When we started this study, there were four or five stinging nettle plants on this end of the field. Now you can see nettle all along the field. We're seeing more and more nettle each year."

20. In point 16, Professor Nantell states that he relied on a private, proprietary marketing survey of farmers in gauging the expected net economic returns to RR alfalfa. The estimated benefits of RR alfalfa, according to this survey, would be $29.30 per acre. It is worth noting that the survey was paid for by Monsanto, the developer of the technology and one of the direct beneficiaries if companies like FGI adopt the technology and incorporate it in their seed varieties. In addition, the opinions voiced by farmers could have reflected, at most one full year of experience with the technology. Given that the true value of any alfalfa variety can only be judged relative to the quality and longevity of the forage stand over four to six years, the

opinions expressed by farmers in this survey could only be based on some combination of the manufacturer's estimates and wishful thinking.

Over the years I have read many reports on agricultural biotechnologies that make projections of impacts based on proprietary, commissioned surveys and studies, like the Monsanto-commissioned study relied on by Professor Nantell for the single most critical number in his economic analysis. Without exception, Monsanto commissioned studies reach conclusions that differ greatly from those of the U.S. Department of Agriculture, virtually all-independent academic analyses, and my own projections (which are usually based on USDA data and methods). Monsanto-commissioned surveys tend to be designed in a way that systematically exaggerates the benefits of a technology, while underestimating the costs of the technology. Plus, Monsanto-commissioned reports rarely address, and indeed usually ignore completely, problems likely to be triggered by the technology (i.e., weed shifts, resistance, gene flow, lost markets, added testing costs, problems with pollinators).

Equally important and understandably, Monsanto-commissioned study designs do not consider the full range of alternatives, nor how farmers actually respond when confronted with a given management challenge. When alternatives are addressed, costs tend to be exaggerated and benefits are understated. While I have not seen the Marketing Horizon survey instrument, it likely reflects the positive experiences of a hand-picked cohort of RR alfalfa producers with limited actual experience with the technology.

21. Professor Nantell, in Table A, projects rapid growth in the acreage planted to RR alfalfa by forage

producers in the absence of the injunction. According to the Professor, area planted rises rapidly from 16,000 in 2005 to 192,407 in 2006, 544,088 in 2007, and then to 1,156,228 in 2008. In 2009 and beyond, the increases slow down to about 50% annually. This pace of commercial adoption would only be expected in the presence of substantial, broad-based economic benefits to farmers. If the added cost of RR alfalfa seed were $10 to $20 per acre, such rapid increases might conceivably occur, if all other problems were to subside. But given the very high premium paid for RR alfalfa seed, it is doubtful that market penetration will proceed nearly as rapidly as projected by Professor Nantell.

22. There are about 21 million acres of alfalfa grown in the U.S. annually, yielding an average of 3.35 tons per acre, or 71,666,000 tons of hay (see Table 8 – Hay: Production, harvested acreage, yield and stocks, USDA National Agricultural Statistics Service). The average stand of alfalfa lasts about four years, implying the need for about 5 millions acres of new plantings of alfalfa each year. Accordingly, Nantell appears to be assuming that in 2007, about 10% of the alfalfa planted nationwide will be RR varieties, and that by 2012, fully 90% of all acres planted to alfalfa will be producing RR varieties.

These assumptions are highly questionable since the technology was developed for and has been marketed predominantly to irrigated alfalfa producers in the West. Growers in the West have higher value land, produce higher yields of better quality hay commanding a higher price, and export a substantial share of their hay to high-value markets abroad. These are the growers that Monsanto and FGI have targeted

as mostly likely to be interested in RR alfalfa. Still, most of the nation's 21 million acres of alfalfa is east of the Rocky Mountains, in areas where alfalfa is largely grown to feed nearby livestock. Farmers in these areas have much less need for RR alfalfa, since a low level of weeds in their crops has modest, if any impact on the livestock feed value of the forage they harvest per acre.

Under the most optimistic assumptions I can imagine, the potential market penetration of RR alfalfa might approach 20% of national acreage, with 80% of the acres planted west of the Rocky Mountains. The economic projections by Professor Nantell are all based on 90% market share by 2012, and for this reason, among others, should be viewed as grossly inflated.

23. Professor Nantell accepts the $29.00 per acre estimate of net farmer benefits to RR alfalfa from the Horizon Marketing study (commissioned by Monsanto) as the basis for his estimate of farm level economic impacts of the injunction—$205 million through 2012 (see Table F). This figure is likely grossly inflated. Indeed, some growers are likely to sacrifice modest income per acre in return for the simplification of weed management inherent in the RR alfalfa system. This has been the case with RR soybeans, corn, and cotton – growers accept higher seed costs and marginally lower per acre profits, in return for the simplicity and efficacy of weed management possible with RR technology (at least for the first three to five years after adoption).

24. In the case of all previously commercialized RR crops, the technology has performed well for the first two to three years. Acceptable to very good weed control in RR soybeans, cotton, and corn was achieved

with just one application of glyphosate on most farms, during the first two-three years of widespread planting. By the fourth year in all of these crops, however, shifts in weed species and the early stages of resistance had, in combination, begun to erode the efficacy of control. It is noteworthy that University of California scientists have already observed shifts in weed species after just three years of experimental plantings (see above for citation).

Farmers have responded by increasing application rates, spraying a second and some times a third application of Roundup, and by adding additional herbicides into their control program. In the Southeast where substantial acreage of RR soybeans and RR cotton overlap, the emergence of several glyphosate resistant weeds has forced many farmers to more than triple their herbicide use compared to the first few years of planting RR crops. In many cases, 2,4-D and/or dicamba have been necessary to control resistant broadleaf weeds. While very low cost to farmers (just a few dollars per acre treatment), these are two of the highest-risk herbicides on the market, posing health risks to applicators and rural community members, and a range of ecological risks to nontarget organisms.

The same pattern will almost certainly unfold with RR alfalfa. Therefore, net benefits to farmers will decline appreciably after two or three years of widespread plantings, and by the fourth or fifth year, the need to apply higher rates and/or additional herbicides will add substantial new costs per acre. Unless FGI and/or Monsanto lowers the premium price for RR alfalfa seed, Professor Nantell's assumption that the net benefit to forage producers will remain

steady at $29.00 per acre through 2012 is inconsistent with the clear record of other RR crops.

25. My 2004 report on the impacts of GE crops on pesticide use from (*Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years*, see Exhibit B), I found that genetically engineered herbicide-tolerant crops resulted in a moderate reduction in herbicide use for two years, with the third year showing no significant change from conventional crop herbicide use. By the fourth year, herbicide use on RR crops (measured by pounds of active ingredient applied per acre) began to rise significantly.

26. Between 1996 and 2004, my analysis showed that herbicide-tolerant crops increased herbicide use by 138 million pounds compared to conventional crops, or by about 5%.

27. Professor Nantell's model also estimates impacts along the supply chain. Clearly, FGI will suffer some losses if the injunction is not lifted, although they have recouped some of their investment in the technology from the first three years of sales. The projected impacts on seed companies and seed dealer-distributors are grossly overstated. These businesses will still sell about the same amount of alfalfa seed, and will earn profit margins per pound of seed that are roughly the same. For this reason, the $8.85 million in projected impacts on seed companies and D/Ds should be markedly discounted.

Impacts on the Organic Sector

28. In weighing the costs and benefits of the injunction, the court should look beyond the company marketing the technology, and those selling RR alfalfa seed, to the full range of impacts across the agricultural

sector. In particular, the commercial planting of RR alfalfa, especially in the West, places in jeopardy the income of farmers growing high-quality hay for export to Pacific Rim countries. This high-quality hay commands a $20 to $30 dollar per ton premium over domestic markets. Assuming average yields of five tons per acre, this premium accounts for between $100 and $150 per acre added income to the farmer.

In addition, RR alfalfa could undermine the now-rapid rate of growth in the production of organic alfalfa, again especially in the West. Organic alfalfa is the backbone of the organic dairy and beef cattle industries. USDA organic production standards prohibit the feeding of any genetically engineered feeds to livestock producing organic dairy or meat products.

29. Pollen flow from one alfalfa field to the next is unavoidable. The planting of a RR alfalfa field near organically managed alfalfa will place in jeopardy the price premium received for the organic hay. This premium ranges from between $20.00 and $50.00 per ton, depending on quality, location, and time of the year. Accordingly, per acre organic premiums are on the order of $80.00 to $200.00 per acre, based on yields averaging four tons per acre. At a minimum to retain market access, many organic hay producers and/or dealers will have to invest in product testing to certify that their hay is GE-free.

30. Production costs are somewhat higher on organic alfalfa farms, and average yields are marginally lower. For these reasons, farmers depend on the price premium to produce positive cash flows. If GE pollen flow into an organic producer's fields were to be detected by a buyer with a zero-tolerance for GE contamination, the organic farmer could lose his/her

market and the premium price needed to sustain the operation economically.

31. If gene flow proves as rapid and pervasive as it has from herbicide-tolerant canola to non-GE canola, the planting of herbicide-tolerant alfalfa will almost certainly curtail the growth of organic alfalfa, and as a direct result, the growth of the organic beef and dairy industries.

32. Organic dairy farming is rapidly growing. The "Food Navigator," an industry e-newsletter, projects 45% growth in the organic diary sector between 2006 and 2011. There are an estimated 500 new dairies in transition to organic production. Dairy processors are actively recruiting new producers to keep pace with strong growth in consumer demand. Fixed-price contracts, sometimes with incentive payments to help farmers through the transition period, are routinely offered. Prices for recently issued organic fresh milk contracts have been around, and sometimes over, $30.00 per hundredweight, over twice the conventional milk price. This large premium will be in jeopardy if RR alfalfa is widely planted.

33. In conclusion, there are several highly questionable assumptions embedded in the analysis of Professor Nantell, all of which inflate the estimate of economic impacts. The reliance on a Monsanto commissioned, proprietary "survey" to project the net value of an acre of RR alfalfa is clearly open to question given the track record of past Monsanto studies and projections.

To the extent there are any net benefits to farmers from RR alfalfa, it is extremely likely those benefits will decline after a few years of harvests. Professor Nantell's assumption that each acre of RR alfalfa will

deliver $29.00 in farm-level benefits each year, through 2012, is highly doubtful.

Given how volatile crop prices are, and in particular the ethanol-driven, dramatic increase in corn prices and planted acreage in 2007, it is clear that many alfalfa farmers could switch to acreage to corn, a "mediating product," at a net benefit to the farmer. This was not taken into account in the Nantell analysis.

Taking all the above factors into consideration, the Nantell estimate of economic impacts—$225 million—is almost certainly high by at least an order of magnitude. Plus, Nantell does not project a number of added costs and adverse economic consequences likely to follow, or which might follow, widespread planting of RR alfalfa. These include increased testing costs to assure that conventional alfalfa does not contain GE proteins; increases in herbicide use and costs; lost markets; and higher costs for organic alfalfa farmers, who will have to take added measures in an attempt to protect their crops from GE-pollen contamination, in addition to sometimes conducting tests to confirm the GE-free status of their harvests.

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 2, 2007, in Enterprise, Oregon.

/s/
Charles M. Benbrook, PhD

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

JA-991

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IPM http://www.pmac.net/

PERSONAL INFORMATION

Birthdate: November 26, 1949
Place: Los Angeles, California
Children: Stephen, Rachel, Michael, Seth and Zacary
Wife: Karen Lutz Benbrook
Hobbies: Work, Fishing, Raising Rabbits, Photography

EDUCATION

B.A. Degree - Economics, Harvard University (1971)
M.A. Degree - Agricultural Economics, University of Wisconsin (1979)

Ph.D.Degree - Agricultural Economics, University of Wisconsin (1980)

EMPLOYMENT HISTORY

The Organic Center, Chief Scientist. January 1, 2006 to present.

Develops and manages a program of research on the environmental and consumer health benefits of organic foods and farming. Responsible for synthesizing new research and science on the impacts of organic and conventional farming systems on food safety, nutritional quality, and taste.

Benbrook Consultant Services (BCS). Sole proprietor of a Troy, Oregon based consulting business. December 1, 1990 to present.

Services for domestic and international clients in the public and private sectors. Major areas of focus include biotechnology; pesticide use, risks, and regulation; adoption and costs-benefits of Integrated Pest Management; impacts of federal environmental laws, especially the Food Quality Protection Act of 1996. BCS specializes in the development of novel methodologies to assess environmental and public health risks and issues. We make heavy use of large government, academic and private sector data sets in shedding light on key policy choices. We maintain extensive, interlinked databases and manage several websites.

Clients include national consumer and environmental groups, international organizations, companies, federal and state government agencies,

trade associations, and academic research organizations.

National Research Council/National Academy of Sciences, Washington, D.C. Executive Director, Board on Agriculture. January 16, 1984 to November 30, 1990

The Board on Agriculture is one of eight major units of the NRC. The executive director is responsible for overseeing and managing activities of the Board and supervising a staff of about 20. Major NAS reports carried out during this period covered the unique risks faced by infants and children from pesticide exposure, modernizing U.S. pesticide regulatory law, pesticide use and resistance, the development and applications of genetic engineering, germplasm conservation and use, animal health and nutrition, the healthfulness of food products and options to improve the safety, agriculture's impact on water and soil quality, and agricultural research and sustainable development needs and challenges.

Subcommittee on Department Operations, Research, and Foreign Agriculture, Committee on Agriculture, U.S. House of Representatives. Subcommittee chaired by Congressman George E. Brown, Jr., Staff Director. April 1981 – January 13, 1984.

Responsibilities of the staff director include: (i) preparing and analyzing legislation within the jurisdiction of the subcommittee (agricultural research system, pesticide regulation, foreign agricultural issues and programs, and plant and animal protection programs); (ii) conducting subcommittee business meetings; (iii) briefing members and staff on legislation

and oversight activities; and (iv) analyzing annual budget proposals.

Council on Environmental Quality, Executive Office of the President, Agricultural Policy Analyst. December 1979 - March 1981.

Responsibilities included: (i) representing CEQ on various Executive Branch committees; (ii) analyzing natural resource data and policy options; (iii) preparing the agricultural section of the Natural Resources chapter in CEQ's 1980 annual report; and (iv) principal author of the Final Report to the President of the National Agricultural Lands Study.

AWARDS OR HONORS

Graduated cum laude from Harvard University, 1971.

Received $1,000 cash award from the Council on Environmental Quality for contributions to the completion of the National Agricultural Lands Study.

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THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) Case No. C-06-01075 CRB
Plaintiffs,	) DECLARATION OF CLINTON SHOCK IN SUPPORT OF PLAINTIFFS PERMANENT INJUNCTION
vs.	
MIKE JOHANNS, et al.	
Defendants,	
and	) Date: April 27, 2007) Time: 11:00 a.m.
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Place: Courtroom 8, 19th Floor) Judge: Hon. Charles Breyer
Intervenor-Defendants.	

I, Clinton C. Shock, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I have a Masters Degree in Horticulture and a PhD in Plant Physiology from UC Davis. I have 38 years experience working in the field and lab, where I have participated in various crop-related projects. I am currently a professor in the Crop and Soil Science Department at Oregon State University and conduct my research at the Malheur Experiment Station in

Ontario, OR, which is located in an alfalfa seed production region of the state. I conduct field trials for various crops, including alfalfa for hay and seed. The opinions that I express are my own and do not represent Oregon State University. My Curriculum Vitae is attached hereto as Exhibit A.

3. Glyphosate has been a really useful tool for agricultural production in the area where my research has been conducted in the Pacific Northwest. Glyphosate has been a very important tool in controlling weeds, including alfalfa. Alfalfa tends to present itself as a weed in other crop fields, including non-RoundupReady (RR) sugar beets and onion. An important strategic technique in weed control is to spray the weeds in a field after planting and just before the intended crop emerges (for example in fields planted to sugar beet or onion). Alfalfa that emerges prior to the emergence of onion and sugar beet is currently controlled with glyphosate.

4. A considerable amount of hard seed is produced by alfalfa plants. Hard seed is generally viable seed that is impermeable to water. Hard seed will not take on water and swell when planted or tested in a germination test. In our alfalfa seed production studies in 2001, 2002, and 2003 hard seed comprised 8 to more than 20 percent of the seed produced. The proportion of hard seed varies by variety, environmental conditions of seed production, and seed treatment among other factors. In a field designated for alfalfa seed production, hard seed will remain in the field for many years after the final year of harvest. If you have a field with conventional alfalfa, there will be conventional alfalfa emerging in the field from hard seed for many subsequent years. Likewise, a field with

RR alfalfa will result in residual RR alfalfa seed within that field. Since hard seed comprises a very significant portion of the total seed that is produced in a field, alfalfa will emerge from hard seed long after the seed crop has been removed. It is simply unfeasible to use a field that has had RR alfalfa grown as a seed crop in the recent past to grow completely uncontaminated conventional alfalfa.

5. RR Alfalfa is different than other RR crops, such as sugar beets, corn and soybean. Without care, cultivation, and planting provided by humans, sugar beet, corn, and soybean plants would not survive. Alfalfa, on the other hand, when left unattended, can thrive as a weed. RR alfalfa planted for forage or seeds can act as a weed in the other RR crop fields. In most other crops, propagation and survival are easy to control. Alfalfa will always produce a certain proportion of hard seed that will come up later, and has the potential to present itself in different RR crop fields, as well as other places where it is not intended. If there are other RR crops in the same crop rotation as RR alfalfa, some weed problems with RR alfalfa can be expected to emerge from hard seed, even if these weed populations are not economic factors in the other RR crops. Because of this inherent property of alfalfa to act as a weed, confining the genetic movement of RR alfalfa will be infeasible in regions where conventional alfalfa seed is grown.

6. East of the Cascades in the Pacific Northwest and across the Northwestern states to the Dakotas, alfalfa acts as a weed. This feral alfalfa grows along roadsides, ditches, and edges of fields, and often grows uncontrolled or may be controlled through mowing, cultivation, or the application of glyphosate and other

herbicides. At present, few of these feral alfalfa plants contain the RR trait. As more RR alfalfa is grown, this will change as the trait is transferred to feral alfalfa. Since many waste areas are occasionally sprayed with glyphosate, the genetic composition of feral alfalfa will shift towards RR alfalfa. It will not be possible to control the flow of the RR trait from these unmanaged areas to production fields because they will be outside of contractual control.

7. In agriculture, uncontrollable events such as windstorms, irrigation ditch breaks, thunderstorms, animal consumption and defecation of seed, and human error are inevitable. For example, a year ago, there was a ditch break on a canal. The water in the irrigation ditch poured out across the fields. Soil and seed was moved in this irrigation ditch break, following the course of the water, into fields, drains and roadsides, regardless of human intent. There was no stopping it. The same would be true in the case of a big thunderstorm. Water carries materials from one field to another. These kinds of things happen in the course of nature and are unavoidable. Since alfalfa always produces a significant portion of hard seed, in the event of a storm or irrigation ditch break, residual seed from previous years can move and contaminate other nearby fields, ditches, and roadsides. For this reason, it may be difficult to grow RR alfalfa in a conventional alfalfa seed production region and still maintain the integrity of conventional alfalfa seed grown in the same area.

8. Many pollinators beyond leafcutter and honey bees such as bumblebees exist in alfalfa fields. Different species can travel different distances. Thus it could be very difficult to limit the spread of RR alfalfa pollen, as neither the pollinator species distribution nor

their distance of travel has been fully documented in alfalfa seed production areas to my knowledge.

9. The argument has been put forward that RR alfalfa hay fields will not genetically contaminate conventional alfalfa seed fields based on contractual agreements that require hay growers to make timely hay harvests, avoiding both pollen transfer from the hay field and seed production within the hay field. These policies demonstrate good intent, but real fields and real weather are not under such tight control. Sometimes wet field conditions or human health do not allow timely operations. Even when most of a field can be harvested, wet spots or corners need to be left unharvested. Areas harvested late can transfer pollen to conventional alfalfa and areas unharvested can transfer pollen and produce seed. Furthermore, towards the end of a growing season, the last cutting simply may not be worth harvesting and it is not unusual for fields or parts of fields to be let go to seed. These factors make it difficult to contain RR alfalfa to a hay field where it has been planted.

10. Because of the factors stated above in convention alfalfa seed production areas, I believe that the traits of RR alfalfa will not be confined, but will eventually be passed to conventional alfalfa seed produced in these areas.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 4, 2007 in Ontario, OR.

/s/

Clinton C. Shock, PhD

THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) No. C-06-01075 CRB
Plaintiffs,	) DECLARATION
vs.	) OF JIM BRIGGS
MIKE JOHANNS,	) IN SUPPORT OF
Defendants,	) PLAINTIFFS
	) PERMANENT
and	) INJUNCTION
	)
MONSANTO COMPANY, FORAGE GENETICS, INC., JOHN GROVER, DANIEL MEDEROS, and MARK WATTE	) Date: April 27, 2007) Time: 11:00 a.m.) Place: 19th Floor, Courtroom 8) Judge: Hon. Charles Breyer
Intervenor-Defendants.	)

I, Jim Briggs, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am a third generation farmer based in Marsing, Idaho. I have been an Alfalfa seed grower in Idaho since 1987. I average about 150 acres of Alfalfa seed production each year.

3. I am a member of the Idaho Alfalfa & Clover Seed Growers Commission, a statwide organization created to improve the alfalfa production and to expand the market for alfalfa and clover seed grown in the state of Idaho. I also serve as an advisor on the Alfalfa

Seed Advisory Board for the Idaho Crop Improvement Association, which gives recommendations to the Idaho Crop Improvement Association Board of Directors on matters related to Alfalfa seed.

4. I currently have a contract to grow non-genetically engineered seed. My contract contains a clause limiting contamination from Roundup Ready traits to 1% contamination.

5. In 2006, Idaho had over 13,347 acres of certified alfalfa seed acres produced in the state and over the last 10 years it has been as high as 35,000 annual certified acres. Idaho is known to be the best area to produce Alfalfa seed and can be based on the fact that most the major Alfalfa seed warehouses are based in the Treasure Valley. Such company's include Forage Genetics, Pioneer Hi-Bred, Dairyland Seeds, Allied seed, Target seed, Price and Sons, Sage Acres, and Vince Holtz Seeds.

6. The potential contamination of my alfalfa seed crop with the Roundup Ready trait is highly probable because alfalfa is a perennial crop which is pollinated by bees. Many bees can pollinate alfalfa seed, including bee species ranging from alkali bees, leaf cutter bees, honey bees, bumble bees, and other natural pollinators.

7. When Roundup Ready alfalfa technology was first introduced and being regulated by USDA in the Treasure Valley, myself and other growers asked Forage Genetics to include growers in the deregulation process. They told me and my fellow alfalfa growers that there was nothing we could do and that they would take care of the matter. Forage Genetics told us that their research showed that 900 feet was an adequate distance for "minimal contamination." I have now learned from "grow out" tests of seed lots from

Dairyland seed in 2006, that the contamination is higher than expected at distances of at least 1.5 miles.

8. The science on genetic contamination also shows that current isolation distances are inadequate. I have read a study funded by Forage Genetics, and prepared by Mr. Bob Hammon from Colorado State University, who performed a pollen flow study in 2006, indicating that biological contamination can occur at 3.8% at 1.7 miles. Myself and other alfalfa growers obtained the Hammon study at the Northwest Alfalfa seed growers meeting in Las Vegas on January 22, 2007. The presentation was given by Mr. Hammon and we later obtained a copy of the PowerPoint presentation from Mr. Hammons on a thumb drive. Attached is a trued and correct copy of the Hammon study as Exhibit A.

9. I have repeatedly asked Forage Genetics about contamination issues from hay fields. Mark McCaslin, President of Forage Genetics, told me and other growers that contamination may not occur if managed properly, and that it would not be an issue. As an experienced alfalfa seed and hay grower of many years, I know this statement is false, because many variables can create conditions that will result in hay plants going into bloom, such as not cutting edges of fields, poor weather, alfalfa growing in waste ditches that cannot be reached and cut, and the timing of custom cutting. Custom cutting is the hiring of a person to come in and cut hay fields at your requested time. Growers often cannot control the custom cutting schedule because of the timing of their request, the numbers of other requests, and the number of acres a custom cutter has to cut before he can fulfill your request. When alfalfa hay plants bloom accidentally,

the pollen can be taken by bees to contaminate other fields. Alfalfa hay fields that are planted during the same season will have overlapping bloom cycles, creating a very real possibility of cross contamination. Additionally, in Idaho there are no restrictions on planting hay and seed fields next to each other. (See web site http://www.idahocrop.com/StandardDocs /Alfalfa-R&R.pdf.) Monsanto is required to collect GPS coordinates for the fields, however they do not release the coordinates to the public.

10. Combining is another potential source of contamination. Some alfalfa seed farmers do not own there own combine, and hire someone to combine their alfalfa seed. Combiners cut Roundup Ready and non-Roundup Ready alfalfa alike. If a combine is moved from a Roundup Ready alfalfa field to a non-Roundup Ready field, left over and hidden seed can mix together contaminating non-Roundup Ready seed stocks. Combiners will clean their combines at request of growers and companies before moving to the next fields, if it is a different species or variety. However, even proper cleaning using high pressure air is not likely to remove all of the seed in the combine.

11. Another source of seed contamination is bins used for hauling seed. Seed storage bins filled in the field and transported to the processing plant can spill seeds unless properly covered with a tarp. Even when seed bins are covered with tarps, however, farmers always reuse tarps, and tarps tear with use allowing some seed to inevitably spill during transport. It is fairly common for seed to be spilled during transport onto farm roads. Some of this seed inevitably ends up next to seed fields.

12. On March 15 2006, I attended an Idaho Crop Association Alfalfa Advisory annual meeting, at the Library Coffee House in Meridian, Idaho. During this meeting, a representative of Forage Genetics named Jose Arias made a motion to reduce the Roundup Ready isolation distance from 900 feet to 165 feet (the standard for conventional seed.) This motion was soundly defeated by the stunned committee members because Forage Genetics failed to offer sound evidence to the committee that addressed the committee's concerns about Roundup Ready contamination.

13. On November 2, 2006, I attended an Idaho Crop Improvement Association meeting in Boise, Idaho. During this meeting, Greg Lowry, Executive Vice President of the Idaho Crop Improvement Association, gave an update in which he described that Dairyland Seed, a major seed warehouse in Idaho, had detected biological contamination with the Roundup Ready gene in its non-Roundup Ready alfalfa in 9 Montana fields, 1 Wyoming field, and 1 Idaho, even where the 900 foot isolation distances were used. Minutes from this meeting are attached as Exhibit B.

14. At the November 2, 2006 Idaho Crop Improvement Association meeting in Boise, Idaho, Doug Gross, a representative of Dairyland Seed, one of the largest alfalfa seed producers in the Idaho, presented information about biological contamination incidents with Roundup Ready alfalfa genes of several of their non-genetically engineered seed lots, including foundation seed lots. Foundation seed is pure seed stock used to propagate more seed for sale. During that meeting it was discussed that seed lots were contaminated. Doug Gross from Dairyland stated that they performed the litmus tests on the seed and after

positive tests, sent samples to an independent lab for "grow out" tests to positively determine the percentage of contamination. A grow out test is a test for biological contamination where a specific amount of alfalfa seed is placed in a tray, germinated, and then sprayed with Roundup. Plants that survive the spraying of the Roundup herbicide are then counted to determine the percentage of Roundup herbicide resistance plants. Dairyland Seed's grow out tests indicated that 11 lots tested positive from a trace to .9 percent contamination at distances up to 1.5 miles.

15. At the November 2, 2006 Idaho Crop Improvement Association meeting in Boise, Idaho, I heard Jose Arias, a representative from Forage Genetics, state that the one lot from Montana at .9 percent could have been contamination from a combine according to the information that they had received. I know for a fact that Forage Genetics knows about the Dairyland contamination events because two representatives from Forage Genetics, Jose Arias and Ken McIntyre, were at the meeting.

16. On November 1, 2006, Steven A. Strachota, President of Dairyland Seed Co., Inc., wrote a letter to Gregory Lowry, Executive Vice President of Idaho Crop Improvement Association, indicating that at least 11 of Dairlyland's non-Roundup Ready seed fields in Montana, Wyoming, and Idaho were contaminated by Roundup Ready alfalfa at distances ranging from 950 feet to 1.5 miles. Doug Gross of Dairyland Seed Co. gave me a copy of this letter after I asked him for this letter in order to inform Idaho growers of the contamination issue with the 2006 seed crop. The hand written numbers on this letter are my handwriting, where I numbered the contamination distances from 1

(least) to 9 (most). A true and correct copy of this letter is attached hereto as Exhibit C.

17. In December, 2006, I wrote and sent out a letter to the members of the Idaho Alfalfa & Clover Seed Growers Association. This letter was edited by Mike Nichols, member of the Board of Directors for the Idaho Alfalfa and Clover Seed Commission and Ron Platt, who is the current President of the Idaho Alfalfa and Clover Seed Growers Association. This letter was then reviewed and approved by the Idaho Alfalfa & Clover Seed Growers Association for distribution. This letter explains to the Idaho growers that the independent testing agency Midwest Seed Lab confirmed that eleven lots of non-Roundup Ready alfalfa seed tested positive for the Roundup Ready gene in fields in Montana, Wyoming, and Idaho at distances ranging from 950 feet to 1.5 miles. I based this letter on data that was presented to the Idaho Crop Improvement Association and research data from Forage Genetics that I obtained from Forage Genetics' website. A true and correct copy of this letter is attached hereto as Exhibit D.

18. On January 16, 2007, I attended the Idaho Alfalfa & Clover Seed Growers Association meeting at the Hampton Inn, in Nampa, Idaho. During a round table discussion, I heard Doug Gross of Dairyland Seed Co. state that Dairyland had confirmed that 16 lots of non-Roundup Ready seed had tested positive for Roundup Ready contamination. Present at the meeting were Jose Arias, and Peter Reisen from Forage Genetics.

19. Based on the evidence given to me by Doug Gross of Dairyland Seed, the research conducted by Forage Genetics, and the research of Mr. Hammon, and

based on my years of experience as an alfalfa seed and hay grower, in my opinion contamination of non-genetically engineered alfalfa with Roundup Ready alfalfa through pollen drift and other mechanisms poses a very real and serious threat to maintaining alfalfa seed stocks free of genetically engineered genes. Given all of this evidence that biological contamination has in fact occurred in seed fields in Idaho, I am very concerned about contamination of my fields. If my fields are contaminated, I would suffer great economic harm.

20. One of the companies I grow for have a contract for non-Roundup Ready alfalfa seed that enumerates a 1% limit on adventitious presence of Roundup Ready alfalfa gene in the seed. If my seeds were to be contaminated beyond 1%, the company has the option to reject the seed or negotiate a lower price. If a seed lot were to turn up positive, I would likely have to destroy the seed crop, thus voiding the remaining years of the contract, which could be up to three years. If my seeds were contaminated during the first year, the company may not want take the chance of any more contamination off of that field, therefore I would have to remove that stand of alfalfa, even though it could remain for several more years. Annually, I could lose approximately $1,300/acre on the affected fields. In 2006 we grew 75 acres of alfalfa seed with contracts containing Roundup Ready clauses. If these 75 acres were to be contaminated, I could be harmed up to $97,000.00 annually. If the contamination came from a hay field next to my seed field, that field may have to be out of seed production until the Roundup Ready hay field is plowed out. In my farming operation, these

fields would be rotated to wheat, which is much less profitable the alfalfa seed.

21. I my opinion, the planting of any more Roundup Ready Alfalfa seed must be stopped until these questions are reviewed in more detail. The continued risk of contamination must be halted until the USDA, Monsanto, and Forage Genetics determine how Roundup Ready alfalfa can be introduced into the United States without contaminating all non-Roundup Ready alfalfa. Alfalfa seed is the second largest seed crop in the state of Idaho, with a cash value to growers of over $16 million dollar, according to the Idaho Seed Indemnity Fund. Idaho alfalfa growers will likely be damaged if contamination becomes widespread, destroying our reputation as the best Alfalfa seed production area.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 3, 2007 in Marsing, Idaho.

_____/s/_____

Jim Briggs

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

[Exhibit A to Briggs Declaration is a duplicate of Geertson Declaration Exhibit A, available at JA-383 to JA-394.]

Idaho Crop Improvement Association
Alfalfa Advisory Committee
Minutes of Meeting, Boise, Idaho
November 2, 2006

Call to Order – Roll Call:

Chairperson Terry Perryman called the November 2, 2006 meeting of the Idaho Crop Improvement Association, Inc. Alfalfa Advisory Committee to order at 09:00 AM.

Committee Members Present:

Carl Norton, Ken McIntyre, Todd Flick, Rod Price, Ray Gross, Doug Gross, Jim Briggs, Terry Perryman, Ross Nishihara, Dave Schuster, Paul Rasgorshek, Steve Norberg

Guests: Greg Lowry, Sam Jennings, Jose Arias, Gerald Hamby, John Hartman, Mike Nichols, Brad Chambers, Sarah Plendl, Mike Hoff, Ron Platt, Lynn Michaels, Peter Royon, Mick Goff, Scott Blake, Ken Morris, Dirk DeBoer

Approval of Minutes, 2005 Alfalfa Meeting:

A motion to accept the previous minutes was made and seconded. Motion was carried. A motion was also carried to not read last year's minutes.

Approval of Agenda

Agenda was approved with no other items added.

Old Business

GMO Isolation

Greg Lowry gave an update of what had been reported back to Idaho Crop Improvement Association. Idaho has been the first state to mandate a 900 foot distance between conventional and GMO plantings. From research conducted in

California the contamination levels were as follows: 300 feet of distance had 1.15% contamination; 600 feet of distance had 0.85% contamination; 2000 feet of distance had as close to zero as possible. Dairyland, using the 900 foot distance between conventional and GMO crops, detected GMO material in 9 Montana fields, 1 Wyoming field, and 1 Idaho field.

The idea of developing production zones for conventional and GMO seed was raised to help alleviate this problem. However, if no tolerance and 100% purity is needed there are areas where the seed can be produced outside of the United States. Approval has been gained for GMO seed use in Japan, Philippines, Mexico, Canada, and the Pacific Rim will be approved in the future.

Both groups, GMO and conventional, want to know where each type of seed is planted. Planning for current and future plantings could be better organized so as to decrease the chance of contamination for either type of seed production. A map with the locations of each type of field would be a valuable tool in trying to lessen the impact of cross contamination of either type. It was decided to have a meeting after today's alfalfa meeting since many of the people who need to be involved in constructing a map were already present. The minutes for the mapping meeting will be available to anyone who has concern over the matter.

New Business

Nominations for Board of Directors

District 2 is in need of representation on the Board of Directors. Those present at the meeting were asked to make nominations for District 2. Kirk Sisson was nominated. Carl Norton initiated the motion of nominating Kirk, and Rod Price seconded the motion. The motion was carried with no opposition.

Nominations for Committee Vacancies

Jim Briggs, Terry Perryman, Ross Nishihara, Dave Schuster, and Paul Rasgorshek all have terms that expire at the end of this year. All of the gentlemen were nominated and confirmed to another term of two years. Paul Rasgorshek was nominated and elected to the position of Chairman of the Alfalfa committee. Ken McIntyre was nominated and elected to the position of Vice-Chairperson.

Other-ICIA Website Development and New Data Base

The data base is still in the initial phases of development, though it will hopefully be beta tested by growers during the 2007 season. Each applicant will be able to track and update their information on the website, though none of their specific information will be available to any other member. All applications will be online, though all applicants will still have to send in the application and supporting documentation to the offices to finalize the process. The website will allow all information, including reporting in the field to be in real time. E-mails will be sent to verify that data has been entered and that the application has been received in the system. Jim Rooney raised the situation of

not being able to use a computer to update the data for every bulk retail sale. The ability to go into the database and record information at a later time needs to be available if possible.

Other-Industry Relations

Greg will put info here

[Logo omitted] **DAIRYLAND SEED CO., INC.**
P.O. Box 958, West Bend, Wisconsin
53095-0958
Phone (262) 338-0163 / Fax (262)
626-2281
1-900-236-0163
www.dairylandseed.com
America's only family-owned seed company with
research in hybrid corn, alfalfa and soybeans

November 1, 2006

Gregory H. Lowry, Executive Vice President
55 SW Fifth Avenue, Suite 150
Meridian ID 83642-8638

Dear Greg:

It has come to my attention that there is a movement afoot to change the acceptable levels of adventitious presence off-types in alfalfa seed from one percent to one and half percent. I object to this attempt to changing the standards in a world where one percent is not thoroughly accepted. Currently there are some countries that have a zero percent tolerance for adventitious presence. This is in seed as well as in hay products. As you may well be aware, currently the Washington State Hay Association does not recommend Roundup Ready seed or hay production at all within that state.

Due to testing and data that was submitted by Forage Genetics, isolation requirements have been established within the other Northwest United States for the production of Roundup Ready alfalfa. While these isolation requirements are at 900 feet, I would like to

point out to you situations we have encountered with regard to some positive Roundup Ready tests on alfalfa seed production in numerous states. These situations are as follows:

State	Acres	Percent Roundup	Distance from RR production	
Montana	16	.4	2600 ft	6
Montana	25	.4	4000 ft	----7-
Montana	25	.3	4000 ft	
Montana	15	.3	1600 ft	4
Montana	35	.9	1400 ft	2
Montana	23	.3	950 ft	1
Montana	26	.2	1500 ft	----3-
Montana	43	.2	1500 ft	
Montana	22	Trace	1 mile	8
Wyoming	26	.3	1700 ft	5
Idaho	2 (foundation)	.2	1.5 miles	9

As you can see, all the fields had adequate isolation according to the 900 foot standard that has been in effect for this past growing season. However, while there is supposed to be little to no contamination beyond the 900 feet, you can see that we broached the 1 percent at 1400 ft. We have even had .2 percent in the foundation field at 1.5 miles. Not only are none of these lots of alfalfa seed exportable to numerous countries in the world, selling this seed in some places in the United States, in particularly Washington State, is not recommended. The contamination of our foundation field with Roundup Ready alfalfa is extremely disconcerting as that seed will not be used for seed production anywhere.

The 900 foot rule was established after Forage Genetics had provided data indicating that leaf-cutter bees did not travel over 900 feet. One of the major fallacies in their research is that they do not take into account the already present native pollinators, which can include honeybees, bumble bees and alkali bees. Therefore I contend that their data is invalid. First and foremost, with this data in hand, I would strongly oppose to changing the current regulation to less than 900 feet.

Due to the fact that there are many countries in the world that will not accept adventitious presence of one percent, I must also vehemently object to changing the off-type standards.

I will be unable to attend your meeting on November 2nd, therefore I am sending our representative, Doug Gross, to carry this message for us. However, I felt that you should have this information prior to the meeting so you know where we stood.

Thank you for your consideration on this matter.

Very truly yours,
Dairyland Seed Co., Inc.

s/Steven A. Strachota

Steven A. Strachota, President
SAS/dsb

pc: Washington State Crop Investment Association; Montana Seed Growers Association; Colorado Seed Growers Association; Wyoming Seed Certification Service; Nevada Department of Agriculture; California Crop Improvement Association; Arizona Crop Improvement Association

[Logo omitted] IDAHO ALFALFA & CLOVER SEED GROWERS ASSOCIATION

55 SW 5TH AVE., SUITE 100 • MERIDIAN, ID 83642 • 208-888-0988 • FAX: 208-888-4586

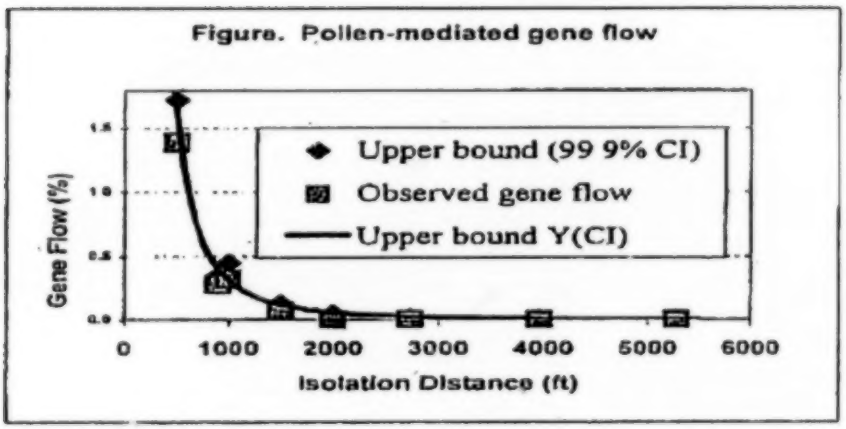
December 2006

As harvest is coming to a close and equipment is being winterized, growers finally have a chance to sit down and review the year as well as put a pencil to how the crops did in 2006. The Idaho Alfalfa/Clover Seed Growers Association thought this would be a good opportunity to bring growers up to speed on the latest developments in the Alfalfa Seed industry.

The Association of Official Seed Certifying Agencies, (AOSCA) is currently taking a recommendation under advisement that would change the genetic purity level of Certified alfalfa seed. Certified alfalfa seed isolation distance is currently set at 165 feet with expected purity being 99.0%. Due to some recent research conducted by Dr. Larry Teuber at University of California Davis, it indicates that this level of purity is not practical and should be changed to 98.5%. This change would give the consumer better representation of the seed that is being purchased, but should not have any effect for seed growers regarding cleanouts. The only exception to this would be genetic purity relating to Roundup Ready contamination in an non-Roundup ready alfalfa seed.

Distance (ft)	Gene flow (%)
50	1.4
100	1.35
165	1.28
300	1.15
600	0.85
900	0.55
1000	0.45
1320	0.13
2000	-0.55

As many growers are aware, this is the second year of Roundup Ready (RR) alfalfa seed on a large scale. States with current production are Wyoming, Montana, Washington, and Idaho. According to research conducted by Forage Genetics during 2000-2002 using Leafcutter bees, the industry was assured that only 900' was needed to prevent gene flow over at an acceptable level. Forage Genetics data indicated at 900 feet gene flow contamination would be approximately 0.28%. At 2000 feet the gene flow contamination would be approximately 0.0%.[1] Honeybees, bumble bees, and other pollinators were not considered in this data.



Based on this data, the industry and Idaho Crop Improvement Association set the isolation distance at 900 feet between RR alfalfa seeds fields and synthetic alfalfa seed fields. Industry agreed that this should keep the gene transfer to an acceptable level of less than 1%.

At the end of the 2006 harvest, some companies began testing genetic purity in alfalfa seed lots using standardized litmus tests. Lots that showed contaminations were then sent to Midwest Seed Lab to conduct grow out tests on the seed. This independent testing agency confirmed that eleven lots of seed tested positive for the RR gene as of November 1 2006. (see chart below)[3] All of the contaminated field exceeded the 900 feet isolation distance, as well as the predicted contamination percentages shown in Forage Genetics 2000-2002 data. The foundation field located in Idaho was approximately 7900 feet from the nearest Roundup Ready field and tested 0.2% from the grow out test. This foundation field cannot be used as seed stock for future production.

During an Alfalfa Seed Advisory meeting at Idaho Crop Improvement Agency (ICIA) on November 2,

2006, industry representatives were asked to explain the contamination of these seed lots. No explanation was offered

Although foreign countries have approved Roundup Ready technology, and Animal and Plant Health Inspection Service (APHIS) has deregulated the production in the United States, the issue remains of how will the markets or buyers accept the technology. Industry agrees among themselves that domestically there is not an issue, except for organic markets, yet Washington State recommends that Roundup Ready technology not be planted for seed or hay production. Export markets such as the European Union are also reluctant to accept the Roundup Ready technology.

Hay and Seed fields

Growers also need to be aware of issues regarding Roundup Ready hay. Industry is currently reluctant to place alfalfa seed fields next to Roundup Ready hay fields, and some companies have clauses in their contracts regarding the matter. At the ICIA meeting, this issue was discussed thoroughly as well as different potential contamination scenarios. When industry representatives were asked who would be liable if a hay field contaminated an alfalfa seed field, they simply responded with "check the liability with Monsanto." It was then stated by industry that they would determine if a grower took appropriate actions to prevent contamination from a neighboring hay field before buying seed showing genetic impurity.

State	Acres	Percent Roundup	Distance from RR production
Montana	16	.4	2600 ft
Montana	25	.4	4000 ft
Montana	25	.3	4000 ft
Montana	15	.3	1600 ft
Montana	35	.9	1400 ft
Montana	23	.3	950 ft
Montana	26	.2	1500 ft
Montana	43	.2	1500 ft
Montana	22	Trace	1 mile
Wyoming	26	.3	1700 ft
Idaho	2 (foundation)	.2	1.5 miles

Forage Genetics 2000-2002 data states, "Under recommended hay management practice it is likely that actual gene flow from hay to seed fields ***may*** be less than 0.2% at approximately 165 ft."[2] (emphasize added). As anyone in the agricultural industry knows, management, weather, custom cutting, mechanical breakdowns, etc., can result in a field blooming during peak pollination periods. In some instances, plants may be missed during the cutting period thus resulting in seeds being produced, such as in the corners of center pivots, wet spots, and waste ditches. Considering these conditions, growers need to be aware of what your neighbor is doing since his growing and cultural practices may exclude you from growing conventional alfalfa seed on lands that you own or rent!!!

The Growers Association's responsibility is to watch out for the interests of all growers and to encourage

the production and sale of high quality Alfalfa and Clover seed. The Association also recognizes that through new technology, agriculture is given new tools to survive in this everchanging world. However, this recent data creates questions as to the accuracy of the pollen flow data on Roundup Ready varieties and synthetics varieties as it relates to genetic purity. We feel that growers need to be aware of this new data and how it may affect their contracts based on genetic purity clauses. Alfalfa seed growers should look at genetic purity language in contracts, since there are a number of different tolerances ranging from 0 to 1 % or more.

Our growers meeting in January 16, 2007 will offer a panel discussion relating to genetic purity and how it may affect growers and the alfalfa seed industry. Information about the Seed School will be mailed after the first of the year.

Future Events

Idaho Oregon Seed School January 16, 2007 @ Hampton Inn, Nampa

38th Winter Seed School, Las Vegas, NV January 22-23, 2007

[1,2] Pollen-mediated Gene Flow in Alfalfa: a three-year summary of field research S. Fitzpatrick, P. Reisen and M. McCaslin Forage Genetics International, West Salem, WI, Nampa, ID, and Prior Lake, MN

[3] Letter obtained from Idaho Crop Improvement dated November 1, 2006.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA –
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants. and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC. and MONSANTO COMPANY, Intervenor-Defendants.	NO. C 06-01075 CRB REBUTTAL DECLARATION OF TIMOTHY J. NANTELL DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Coutroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

Analysis and Opinion in My March 23, 2007 Report

1. I filed a report in this matter on March 23, 2007. My qualifications were outlined at the beginning of that report.

2. For my March 23, 2007 report, I was asked by Forage Genetics Inc. ("FGI") and RRA grower intervenors (collectively "intervenors") to calculate the economic impact on the members of the RoundUp Ready Alfalfa ("RRA") production and sales chain[1] of an injunction which would prohibit

[1] The RRA production and sales chain includes the RRA seed growers, Forage Genetics, Inc. ("FGI"), which buys the RRA

the continued planting of RRA, pending the completion of an Environmental Impact Study ("EIS") by APHIS. In estimating the economic impact of an injunction during the time of the EIS, I was asked to assume that the EIS will be completed and the injunction removed in time for planting to be resumed in fall of 2009. I was also asked to assume that forage farmers may continue to grow and harvest any RRA that is already planted as of March 31, 2007, and that seed farmers may continue to grow and harvest RRA seeds under contracts with FGI from plants that were already in the ground by March 31, 2007, although the seed produced must be stockpiled and may not be planted until the EIS is completed.

3. My March 23, 2007 report presented the results of my analysis under these presumed conditions. I concluded, based on certain conservative estimates, that the economic impact on the members of the RRA supply chain of an injunction during the time of the EIS would be, approximately, a lost contribution margin (lost profits) of $225 million, net of all reasonable mitigation offsets throughout the supply chain.[2]

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seeds from the seed growers and sells them to seed companies, seed companies, seed dealers and distributors and the RRA forage growers who plant the RRA seeds and harvest the forage they produce.

[2] I was not asked to estimate, nor does the $225 million include, the impact of an injunction on Monsanto. Nor was I asked to calculate the economic impact of the absence of an injunction on the plaintiffs.

4. The economic analysis of an injunction in this case calls for consideration of four general possible scenarios:
   - injunction during the EIS, followed by RRA deregulation,
   - no injunction during the EIS, followed by RRA deregulation,
   - injunction during the EIS, followed by RRA regulation, and
   - no injunction during the EIS, followed by RRA regulation.

   In my judgment, the analysis called for in considering the economic impacts of an injunction during the EIS period requires trading off two conflicting interests:
   - the economic impact on the intervenors of an injunction during the EIS period should the EIS again lead to deregulation of RRA, and
   - the economic impact on the plaintiffs of no injunction during the EIS should the EIS lead to continued regulation of RRA.
5. At the request of the intervenors, I prepared a report, my March 23, 2007 report, that presented my estimate of the first of the two conflicting impacts: the impact on the intervenors of an injunction during the EIS should the EIS lead again to deregulation of RRA. I was not asked to, nor did I, undertake an analysis of the second of the two conflicting impacts: the impact on the plaintiffs of no injunction during the EIS period should the EIS lead to continued regulation of RRA. It was my implicit assumption that my estimate of the economic impact of an injunction on

the intervenors would be used by the court to compare to an estimate of the economic impact of no injunction on the plaintiffs as estimated by the plaintiffs.[3]

Plaintiffs' Response To Intervenors' Memorandum

6. On April 6, 2007, plaintiffs filed a Response to Intervenors' Memorandum Regarding Permanent Relief, dated March 23, 2007. This response from plaintiffs ("Plaintiffs' Response") made reference to a number of declarations provided by various parties associated with the plaintiffs, including a number of organic alfalfa growers and consumers (i.e. dairy farmers) and parties representing organic alfalfa growers and consumers and including Charles M. Benbrook, PhD and Chief Scientist at the Organic Center.

7. Dr. Benbrook's declaration covers two topics—a critique of my March 23, 2007 report and a section titled Impacts on the Organic Sector. The declarations from alfalfa growers and consumers and from related associations provide, for the most part, comments with respect to their perceptions regarding the impact on the revenues for their individual businesses should their organic alfalfa fields or their purchased organic alfalfa forage become contaminated with RRA.

8. I have been asked by the intervenors to:

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[3] The incremental economic impact on the intervenors of an injunction during the EIS should the EIS lead to continued RRA regulation is presumed to be relatively small. Likewise, the incremental economic impact on the plaintiffs of no injunction during the EIS should the EIS lead again to RRA deregulation is presumed to be relatively small. For this reason, little analysis has been devoted to those scenarios.

- respond to Dr. Benbrook's critique of my March 23, 2007 report,
- comment on the relevance of Dr. Benbrook's claims in the section of his report entitled Impacts on the Organic Sector to the question of the economic impact on the plaintiffs of no injunction during the time of the EIS study, and
- comment on the relevance of the claims made in the other declarations with respect to the question of the economic impact on the plaintiffs of no injunction during the time of the EIS study.

9. The remaining three sections of this declaration provide my opinions with respect to each of the above three items, although I will do so in reverse order.

Claims Made By Organic Alfalfa Growers and Consumers

10. I was presented with and reviewed a number of declarations by organic alfalfa growers and consumers and by parties associated with organic alfalfa growers and consumers ("the relevant declarations"). (The attached list of Materials Provided to me includes a list of these declarations.) Plaintiffs' Response includes its own summary of the content of these relevant declarations in a section entitled The Use of Roundup Ready Alfalfa and the Resulting Contamination Will Harm Organic and Conventional Farmers (pp. 13-15).

11. The summary of the relevant declarations included in this section is consistent with its title and with my own opinion regarding the claims made in the relevant declarations. That is, the Plaintiffs'

Response makes no claim that the relevant declarations provide estimates of the economic impacts on the declaring parties of the absence of an injunction during the EIS period. Nor do I see anything in the relevant declarations that speaks in any way to the specific question of how an injunction during the time the EIS is completed impacts any of the declaring parties. In other words, there is nothing in the relevant declarations, nor in the summary thereof in Plaintiffs' Response, that provides an estimate or estimates of the economic impact on the plaintiffs of no injunction pending the completion of the EIS. The relevant declarations, therefore, provide nothing to compare to the estimated $225 million impact on the intervenors of an injunction during the EIS period in my March 23, 2007 report.

12. And, given what the relevant declarations did say, it is not possible to use them to come to any conclusions regarding the magnitude of the economic impact on the plaintiffs of having no injunction during the EIS. For example, although the declarations are less clear than they might be, it appears that most, if not all, of the claims made have to do with revenue impacts, not profit impacts.[4] A number of references are made to the fact that premium prices for organic products are needed to offset the higher cost of producing the organic products. In such a case, it is critical to identify the impact of having no injunction during the EIS period on the profits of the parties, but the

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[4] And it bears repeating that none of the claims have anything to do with the impact of not having an injunction while the EIS is being completed.

claims made in the relevant declarations do not refer to profit impacts at all, just revenue impacts. Such statements fall irretrievably short of providing the relevant impacts on the plaintiffs should there be no injunction during the EIS period. Not only does this failure violate the general guidelines for how to estimate economic impacts, but it also leaves the court without a benchmark against which it can compare the $225 million I found in my March 23, 2007 report as the economic impact on the intervenors should there be an injunction during the EIS period.[5] And this is only the first of three critical shortcomings to using any of the estimates provided by the plaintiffs for the purpose of estimating the economic impact on the plaintiffs of no injunction during the EIS period.

13. The second critical shortcoming in the claims made in the relevant declarations is that few, if any, of them adjust the claims made for reasonable mitigation attempts that could be made by the relevant parties to reduce the impact. It is always important to include the offset from reasonable mitigation efforts available to the parties during the time of the injunction as a means of minimizing the impact of the injunction, and yet no such

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[5] It goes without saying that plaintiff estimates are not really estimates at all of the economic impact on them from the absence of an injunction during the EIS, and, as such, any amounts the plaintiffs refer to cannot be compared to the $225 million estimate of the economic impact on the intervenors from a continued injunction during the EIS that I reported in my March 23, 2007 report. To compare any of the amounts the plaintiffs mention to the $225 million impact I estimate for the intervenors is to compare apples and oranges.

mitigation impacts were discussed in any of the relevant declarations.[6]

14. The third critical shortcoming, and perhaps the most significant shortcoming with respect to the amounts mentioned in the relevant declarations, is that most, if not all, of the monetary claims made in the relevant declarations are said to be relevant only **IF** their organic fields and feed are indeed contaminated with RRA alfalfa. No attempt is made in any of the relevant declarations to identify, or even analyze, the impact the absence of an injunction during the EIS period would have on the number of plaintiffs' fields or feed that would in fact become contaminated. In other words, the question with respect to the economic impact of lifting the injunction during the period of the EIS is not what will happen to plaintiffs assuming all their properties become contaminated, but how many of their properties are likely to become contaminated specifically because the injunction is lifted during the time it takes to complete the EIS.
15. This is central to the relevance, or lack thereof, of the plaintiffs' declarations to the question of economic impact from the removal of the RRA injunction during the time of the EIS. To be

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[6] Again, as mentioned above with respect to the fact that the amounts mentioned by the plaintiffs are revenue impacts, not profit impacts, the fact that these amounts are also not reduced for reasonable mitigation efforts means they cannot be compared to the $225 million estimate of the economic impact on the intervenors from a continued injunction during the EIS period that I reported in my March 23, 2007 report. To compare any of the amounts the plaintiffs mention to the $225 million impact I estimate for the intervenors is to now doubly comparing apples to oranges.

specific, and to wrap together all three shortcomings inherent in the relevant declarations, the economic impact on the plaintiffs from the absence of an injunction during the time of the EIS is not the plaintiffs' loss of revenues from their organic fields and feed under the assumption that they are all contaminated, and under the assumption there are no alternative mitigating activities the plaintiffs could, and likely would, turn to mitigate the economic impact. Rather, in my opinion, the standard regarding the economic impact on the plaintiffs due to the absence of an injunction during the EIS period is the loss of net profits (the loss of revenues net of the expenses incurred to generate those revenues, usually an amount that is substantially lower than the loss of revenues) to only those plaintiff properties that are estimated to become contaminated during the period of the EIS specifically because of the absence of an RRA injunction during that time (the properties contaminated during that period because of the absence of an injunction that would not have become contaminated had there been an injunction during the time of the EIS study), net of the economic gain to the plaintiffs from the alternative activities they undertake because their properties were contaminated during the EIS period.[7]

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[7] Put another way, there is a fundamental difference in the nature of the economic impact of the absence of an injunction on the plaintiffs and the economic impact of a continuing injunction on the intervenors. As we have just discussed, the question for the plaintiffs, one they do not directly address, is how will the absence of an injunction, specifically, while the EIS is being completed,

16. Unfortunately, there is nothing in the relevant declarations, nor in the summary thereof in Plaintiffs Response, that even addresses this central question, much less sheds any light on the answer to it.
17. In estimating the economic consequences on the intervenors from a continuing RRA injunction during the time of the EIS to be $225 million, I was attempting to measure the loss of net profits (which I referred to as lost contribution margin) to only those intervenors that would indeed be affected by the injunction (and would not have been affected in the absence of an injunction during this period), net of all mitigating behavior the intervenors could reasonably be expected to pursue should they be so affected. Nothing in the relevant declarations provides anything even close to an economic impact on the plaintiffs based on the same sound standard.
18. In conclusion, considering that the relevant declarations do not claim to be speaking to the question of how the plaintiffs would be affected by the absence of an injunction while the EIS is being completed, considering that the Plaintiffs' Response recognizes that the relevant declarations make no claims regarding the question of how the declaring parties would be affected by the absence

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affect the number of organic fields and feed that become contaminated—what are the probabilities. There is no such corresponding probability question when investigating the impact of an injunction on the intervenors. No RRA forage fields, with 100 percent certainty, will be replanted should an injunction be granted. No additional RRA seed fields, with 100 Percent certainty, will be planted should an injunction be put in place for the EIS period. And so on.

of an injunction while the EIS is being completed, considering that the amounts that are referred to in the relevant declarations are revenue amounts and not net profit amounts, considering that the amounts that are referred to in the relevant declarations are not net of reasonable mitigation efforts, and considering that none of the amounts referred to in the relevant declarations are for only those properties that are likely to become contaminated only because of the absence of an injunction during the time of the EIS, it follows that it is not possible to use these amounts to come to any conclusions regarding the magnitude of the economic impact on the plaintiffs from the absence of an injunction during the EIS.

Claims Made By Dr. Benbrook Re Impacts on the Organic Sector

19. Dr. Benbrook devotes roughly a single page (bottom of p. 10 through the bottom of p. 11) to what he labels Impacts on the Organic Sector. In opening my comments on this part of Dr. Benbrook's declaration, it is important to note that in this section, Dr. Benbrook does not attempt to provide the critical estimate—the economic impact on the plaintiffs due specifically to the absence of an injunction during the completion of the EIS—to compare to my estimate, presented in my March 23, 2007 report, of $225 million in economic impact on the intervenors should there be an injunction during the completion of the EIS.

20. Rather, as was the case with the relevant declarations discussed above, Dr. Benbrook spends the one page he devotes to this question talking about revenue impacts under the assumption that

organic fields are contaminated with RRA alfalfa and without regard to mitigation opportunities. As discussed above, for a number of reasons this is not, in my opinion, the central question with respect to the issue of the economic impact on the plaintiffs due to the absence of injunction during the completion of the EIS. Dr. Benbrook's analysis of the impacts on the organic sector is quite similar in kind to the claims made in the relevant declarations. I will not repeat here the discussion in the previous section of all the ways in which this analysis falls short of what is required. Suffice it to say that Dr. Benbrook's analysis falls just as short of the relevant estimates as was the case for the relevant declarations.

21. In the case of Dr. Benbrook, his failure to deal with some of the relevant issues is somewhat surprising for at least a couple of reasons. In the first place, he realizes that high production costs and low yields in organic farming at least partly drive the premium prices he and others refer to (paragraph 30 on p. 11). In fact, he might be suggesting that after consideration of the higher production costs and lower yields in organic farming, the premium prices merely put the organic farmer back at a non-premium contribution margin (paragraph 30; second sentence). Yet he still refers to premium prices rather than profit impacts when discussing "impacts on the organic sector."

22. Second, Dr. Benbrook's one page of analysis of the "impacts on the organic sector" comes after almost seven pages (pp. 4-10) of comments on my analysis of the economic impact on the intervenors of an injunction while the EIS is being completed. Dr.

Benbrook chose to correct none of my supposed errors in his own analysis of the "impacts on the organic sector." This is consistent with my opinion that none of the claimed errors in my report are errors at all.

Dr. Benbrook's Critique of My March 23, 2007 Report

23. In Dr. Benbrook's seven pages of criticism regarding my estimate of $225 million as a reasonable estimate of the economic impact on the intervenors from an injunction while the EIS is completed, he basically claims the following errors on my part:
    - that the basic structure of my analysis was presumptuous in a number of ways,
    - that RRA seed growers would be better off letting their plantings go to forage,
    - that I overstated the likely growth in RRA forage acreage,
    - that seed companies and dealers/distributors would not lose anything should an injunction be enforced while the EIS is completed and
    - that he doesn't accept the $29 per acre advantage I used for RRA forage growers, either now or in the future.
24. The Nantell March 23, 2007 Analysis Is Appropriately Presumptuous. Dr. Benbrook's first point seems to be that I shouldn't have completed my analysis under the assumption that the EIS would lead to deregulation of RRA and that I shouldn't have assumed a two year period for the completion of the EIS. In my judgment he is fundamentally wrong on both counts.

25. With respect to the first claim, that I shouldn't have calculated the economic impact on the intervenors under the assumption that the EIS study would lead again to a deregulation of RRA, in my opinion, this reflects a fundamental misunderstanding on Dr. Benbrook's part of what is called for when trading off economic consequences to the various parties in the context of addressing the economic impact of an injunction. As addressed earlier in this declaration, the exact question, from the intervenors' point of view, is precisely one of what impact an injunction will have on them should the EIS eventually reinstate RRA deregulation; i.e. what short-term economic costs did they incur while the EIS process was ongoing.. These specifically are the conditions the intervenors are in fact concerned with when it comes to the question of whether there should be an injunction.[8] Just as the plaintiffs are interested in what impact the absence of an injunction will have on them should the EIS eventually establish regulation of RRA beyond the EIS period. Interestingly, Dr. Benbrook did not do, for his part, exactly what he claims he wanted me to do for my part. That is, he did not analyze the economic impact on the plaintiffs due specifically to the absence of an injunction should the EIS lead again to RRA deregulation. He apparently did not consider that to be inappropriately presumptuous; neither do I. And neither was the structure of my analysis inappropriately presumptuous—it is

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[8] The intervenors are also interested in whether RRA should be deregulated, but that is now a question for the EIS, and independent of whether there should be an injunction.

rather, in my opinion, exactly what is called for. I will not repeat here again my description of that structure, but I direct the reader to my earlier comments in this regard in paragraphs 4 and 5 above.

26. As to the question of how long the EIS study will take, I was asked to assume that it would take two years, which is what I used in my March 23, 2007 report. However, I also determined that a two year EIS period was as favorable to the plaintiffs as I could reasonably be. In other words, as is standard in preparing the kind of analysis I presented in my March 23, 2007 report, where there can be honest differences of opinion regarding estimates such as the length of time the EIS will take, I opted for an estimate that would, if anything, understate the economic impact of a continuing injunction on the intervenors. That is, I used a two year period for the EIS because that was a conservative, yet reasonable estimate. I say it was a reasonable estimate because I didn't find any claims that it would likely be significantly less than two years. I say it was a conservative estimate because if I had a used a longer estimate as Dr. Benbrook seems to be suggesting, a three year estimate or a three and one-half year estimate or longer, the negative economic impact on the intervenors would be even larger than the $225 million I estimated.

27. In addition to this defense of using a two-year EIS period in my March 23, 2007 report, it's one thing for Dr. Benbrook to call that into question (perhaps because he was unaware of the consequences for the estimated economic impacts on the intervenors

of a longer EIS period), but, having called it into question, I do note that he did not propose an alternative. I have already noted that had he done so and had his recommendation been for a longer period, the negative consequences on the intervenors would be even larger than the $225 million I estimated. In addition, Dr. Benbrook did not, apparently, need to address a specific EIS period in his comments in Impacts on the Organic Sector is only because, as discussed in more detail earlier, he did not really ever estimate the impact of the specific absence of an injunction during the time of the EIS on the plaintiffs' net profits net of mitigation offsets. In fact, noting his failure to set a length of time for the EIS is one way of emphasizing that he did not ever really estimate the impact of the absence of an injunction on the plaintiffs.

28. RRA Seed Growers Should Not Become RRA Forage Growers. Apparently, as one approach at RRA seed grower mitigation during the time of the EIS study, under the assumption that there is an injunction in place, Dr. Benbrook suggests that RRA seed growers let their seed crop go to forage and harvest the RRA forage and sell that rather than continue to sell its RRA seed harvest to FGI during the EIS period. It is not clear to me exactly what effect Dr. Benbrook thinks this switch in the underlying business model for the RRA seed growers will have on my estimated $225 million in intervenor losses due to a continuing injunction during the time of the EIS. In my judgment, it will make the negative impact of an injunction on the

intervenors more negative, for a number of reasons.

29. First, it's my understanding that the entire production model for growing RRA seed is quite different from growing RRA forage and moving from one production mode to the other is no simple matter. Nor are the economic advantages obvious for one grower who has become proficient at RRA seed growing to suddenly switch to RRA forage growing. The production techniques are different, the inputs are different, the markets are different, seed growing works best in some locations and forage growing best in others, and so on. Dr. Benbrook did not lay out the details of his proposal, so it is hard to see how what he had in mind could overcome these difficulties.

30. Second, the $225 million negative impact on the intervenors from a continuing injunction during the EIS period already includes a pretty good mitigation plan for the RRA seed growers, one that is likely superior for all parties concerned to telling them to abandon their chosen business model in favor of another vaguely defined one. In my analysis, the seed growers continue doing what they think they do best—grow RRA seed—on the RRA seed acres in place in the spring of 2007. And as would be the case in the absence of an injunction, FGI is assumed to continue to buy the RRA seed they grow. That strikes me as a pretty good mitigation plan for the RRA seed growers.

31. Third, as for the reduced acres and FGI contracts available to the RRA seed growers caused by the injunction, my $225 million estimated economic impact includes a mitigation product for those

acres as well.[9] Dr. Benbrook has made no suggestion that letting the RRA seed go to forage will in any specific way reduce the $225 million negative estimated impact on the intervenors.

32. Fourth, the key to keeping the economic impact on the intervenors from an injunction during the EIS period as low as possible is to get the RRA forage acres after the EIS period back to where they would have been without an injunction as fast as possible. One way to contribute to this is to have FGI stockpile RRA seed during the EIS period by buying it from the RRA seed growers during that time so that it can quickly be sold to the RRA forage growers once the EIS period is over. Dr. Benbrook's proposal would work in the opposite direction.

33. Finally, it is surprising that Dr. Benbrook focused on this presumed inadequacy in my approaches to maximizing mitigation offsets for the intervenors when he did so little in his Impacts on the Organic Sector to make sure he had carefully considered specific mitigation strategies for the plaintiffs. Looking through Table B through Table F in my March 23, 2007 report will show that I have clearly identifiable mitigation strategies for each member of the RRA supply chain. Dr. Benbrook's Impacts on the Organic Sector, which took up roughly one page in his report, has little to nothing to say about mitigation opportunities for the plaintiffs.

34. The March 23, 2007 Nantell Report Does Not Overstate RRA Forage Acre Growth. Dr. Benbrook claims in a number of different places

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[9] See lines 8-10 in Table B of my March 23, 2007 report.

that my March 23, 2007 report overstates the future growth in demand for RRA forage. Unfortunately, this judgment appears to be based largely on a misreading of Table A in my March 23, 2007 report. With that misreading on his part corrected, his claim largely disappears.

35. Dr. Benbrook apparently thinks that the estimates made in my March 25, 2007 report are based on an assumption that RRA forage acres will, by 2012, comprise 90 percent of all alfalfa acres. Dr. Benbrook is wrong. Dr. Benbrook's own estimate, based on USDA sources, is that 21.3 million acres of alfalfa are currently harvested annually in the U.S. (see paragraph 21 in Benbrook). Lines 60-62 in Table A show clearly that, without an injunction, I am estimating RRA forage acres harvested in 2012 at 4.5 million, the sum of the three numbers in those lines for 2012. Even ignoring the growth in U.S. alfalfa acreage between now and 2012, my 2012 4.5 million RRA forage acres is only 21% of the total alfalfa acreage of 21.3 million acres, nowhere near Dr. Benbrook's claim that I was using an RRA forage acreage of 90 percent of the total alfalfa acreage.

36. Dr. Benbrook's error appears to come from misinterpreting lines in my Table B labeled "Forage Acres Planted." (See Lines 51, 55 and 59 in Table B.) His claim that I have RRA forage acres at 90 percent of all alfalfa acres is based on comparing the sum of these three lines in Table A for 2012 to his translation of the USDA 21.3 million in total alfalfa acres into 5 million acres of "new plantings of alfalfa each year." (Benbrook paragraph 22) That calculation does yield a 90

percent result—(829,396 + 3,189,986 + 535,918) / 5,000,000 = 91 percent. However, this calculation by Dr. Benbrook is comparing apples to oranges. The lines in Table A labeled "Forage Acres Planted" do not refer to new annual plantings, but total plantings. I think this is clear to anyone following Table B and seeing how those lines are used, including their equivalence to other lines labeled as "Forage Acres Harvested." (Lines 60-61) Plus there are lines in Table A labeled "Forage Acres Added" (Lines 50, 54 and 58), so it's hard to see how Dr. Benbrook could have interpreted "Forage Acres Planted" as newly planted acres, but that misinterpretation is what lead him to conclude that I overestimated RRA forage demand by an order of magnitude.

37. As indicated two paragraphs above, correcting Dr. Benbrook's error leaves the RRA acreage at 21 percent of total alfalfa acreage, by 2012. This is a very reasonable estimate. First, it is consistent with FGI's internal estimate of RRA forage acres by 2012, an estimate used in their business cases and an estimate made in the normal course of business. It is also consistent with RRA soybean and corn market shares. It's also consistent with the quick launch RRA forage enjoyed since deregulation in June 2005. Finally, it is also in the range that Dr. Benbrook himself finds acceptable —"under the most optimistic assumptions I can imagine, the potential market penetration of RRA alfalfa might approach 20% of national acreage." (Benbrook paragraph 22)

38. Seed Companies and Dealers/Distributors Will Lose From An Injunction. Dr. Benbrook claims

that my estimated $8.85 million in negative economic impact from an injunction during the time the EIS is completed for the seed company and seed dealer/distributor ("D/D") members of the RRA supply chain should be "markedly discounted." (Benbrook paragraph 27) He offers one additional sentence by way of explanation, which says only that the same amount of alfalfa seed will be sold through the chain by the seed companies and seed D/D and for not that much of a lower margin.

39. Dr. Benbrook chose not to explain how it is that the usual result in supply chains would not apply to RRA seed. The standard economics is that as a premium item, a higher value added item, works its way through its supply chain, every member along the chain enjoys some added margin from that item compared to their margins on lower value added items. In my experience, it would be an unusual supply chain where this is not the case.

40. Given the standard economic situation and given my own experience over the years, I expected this to be the case for RRA seed as well. In other words, I expected that the seed company and D/D margins on RRA would be higher than was the case for lower premium seed. At the time I was developing the estimates to feed into my economic impact model for my March 23, 2007 report, I addressed that very question by talking to FGI personnel familiar with the margin experiences of seed companies and D/D. They provided information that made me feel comfortable that the standard economics of supply chains did in fact apply to the RRA supply chain as well. Table D

and Table E in my March 23, 2007 report reflect a conservative premium for RRA margins versus the margins on replacement seed relative to the information gleaned from my conversations with FGI personnel. The loss in margin of 50 percent reflected in Table D for the seed companies and in Table E for the D/D companies from selling the substitute seed in place of RRA seed (so as to mitigate the economic consequences of the RRA injunction) is right in line with the fact that the retail price of the substitute seed is generally half the retail price of RRA seed.

41. In addition, Dr. Benbrook claims that these seed companies and D/D would sell the same amount of seed with or without an injunction during the time of the EIS. Although I think supply problems and changed customer/distributor relationships make that an aggressive assumption on his part, I adopted exactly that estimated to be conservative in my March 23, 2007 report. But I did this because, in setting the economic impact of the injunction, I wanted to be careful to offset the negative impacts with any mitigating benefits the various parties might be able to undertake. So, each one of the tables in my March 23, 2007 report, Table B through Table F, consider mitigation possibilities for each link in the RRA supply chain and contain specific and substantial offsets to the underlying negative economic consequences, thereby lowering the level of economic consequences from what they otherwise would have been.

42. What is surprising to me is that Dr. Benbrook wants to focus on my mitigation estimates when he

completely avoided any mention of mitigation at all when considering the impacts of the absence of an injunction on the organic growers and customers. There is no mention of mitigation offsets for any plaintiffs in his one page devoted to Impacts on the Organic Sector in his declaration.

43. March 23, 2007 Nantell Report Does Not Overstate Economic Advantages To RRA Forage. In arriving, in my March 23, 2007 report, at an estimated $225 million in negative economic consequences for the intervenors, I estimated that the economic advantage to RRA forage averaged $29 an acre. Dr. Benbrook, in a number of different places in his declaration, and stated a number of different ways, disagrees. It is not perfectly clear what he thinks the advantage per acre should in fact be set at, but he does not think it is $29 per acre. I think that the $29 per acre estimate that I used is actually a conservative estimate.

44. First of all, it seems quite clear that whatever the specific advantage per acre for RRA forage is, it is quite substantial. From deregulation in June 2005, when roughly 5000 acres of RRA seed were harvested, the demand for RRA has exploded so fast that FGI's business plan calls for having contracts for 24,000 acres of RRA seed planted by fall of 2007 (in the absence of an injunction). These numbers are important because they reflect the demand that FGI sees in the market place for RRA seed. Going directly to the product market for the RRA seed, RRA forage growers, RRA forage acres harvested have exploded from nothing in 2005 to almost 500,000 acres in 2007 (in the

absence of an injunction). Both of these growth patterns speak volumes with respect to how much advantage forage growers see in RRA forage over other types of forage and substitute products.

45. With years of experience in looking at market acceptance or rejection of new products, when I saw these adoption rates right out of the gate, I surmised that there likely were large economic advantages associated with the use of RRA forage, net of its premium price. I read as much as I could find in the existing court record at that time in order to see if I could see the sources of these advantages. I also talked with FGI personnel to get their perspective as to the sources of the advantages of RRA.. Out of this it became clear that there were yield advantages, raw material input efficiencies, reduced labor costs and equipment costs, benefits to the land, and convenience for the grower. And the market's easy acceptance of a premium product told me that these were more than claims.

46. At that point the evidence confirmed that there were advantages for RRA forage above and beyond the premium price for the RRA seed, but I didn't yet have a means for quantifying that advantage in some convenient way, e.g. net added contribution per acre of RRA forage. As a means of filling this gap, I initially considered talking to a small sample of RRA growers and seeing if they had records or any other means that would allow me to quantify the advantages of RRA forage. The small size of the sample, the difficulty in organizing an independent sample and a short time frame made such an approach problematic. At that point

I started searching for alternative means of estimating the advantage to RRA forage. I knew that agricultural people were comfortable talking about advantages in terms of per acre or per cow or hog or per hundredweight and so on.

47. In searching around for an independent means for estimating the advantage of RRA forage, I eventually was told about the Monsanto study that I referred to in my March 23, 2007 report.[10] This study reported the results of a survey of forage growers done outside the scope of litigation, i.e. a survey undertaken in the normal course of business by a marketing research company, Marketing Horizon's Inc. at the request of Monsanto. A statistically selected sample of 356 forage growers were asked to monetize the advantages of RRA "taking into account any differences in yield, quality of hay, convenience, labor, peace of mind, weed control, seed costs, and herbicide costs."[11] Although the improvements provided by RRA varied in the minds of the interviewees, it was estimated on average that the benefits, across price ranges and across the country, amounted to $29.30 per acre. Of course some growers saw substantially higher advantages and others not so high.

48. The point is, however, that a large sample of a range of independent forage growers have estimated the advantages of RRA forage net of its higher seed costs and have spoken up, the advantage is positive. And from the above data on

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[10] "Roundup Ready Alfalfa Satisfaction Study," Marketing Horizons, Inc, November 2006.

growth rates in RRA seed acreage and RRA forage acreage, these are not hypothetical advantages. These growers have put their money where they saw these advantages.

49. Dr. Benbrook doesn't like Monsanto surveys, but he presents no supporting evidence to support a claim on his part that Monsanto surveys cannot be relied on. These, of course, are not Monsanto surveys; they are the surveys of a highly reputable marketing firm whose business is specializing in the design, execution and interpretation of such surveys. All things considered, especially the consistency between the survey results and the rapid market acceptance of RRA, the evidence in the survey is, in my opinion, quite reliable.

50. In addition, there are a number of other independent/academic studies confirming the advantages of RRA, as summarized in documents on FGI's web site.[12] In these summary documents, as in the survey, the range of benefits is wide, but they are all positive and substantial. And these advantages tend to focus on just the yield advantages. Compare these advantages to the premium price for RRA seed, on the order of $3 per pound of RRA seed, and factor in the pounds of RRA seed required per acre of RRA forage (on the order of 18 pounds of RRA seed per acre of RRA forage) and the number of years an acre of RRA produces forage before it needs to be replanted (on the order of four to six years) and factor in advantages beyond yield and the $29 per acre per

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[12] http://www.roundupreadyalfalfa.com/viewlist.aspx?list=regions

year RRA advantage I used in my March 23, 2007 report looks quite reasonable, if not conservative.[13]

51. Dr. Benbrook makes vague references to other products that he claims RRA forage growers should grow instead, for example, corn for ethanol production. These judgments are too vague and unsupported by careful analysis to be of any practical use. The kind of vague statements Dr. Benbrook makes in this regard have not been, and, given the information he has provided, cannot be subjected to careful analysis to determine whether the claims he makes can be substantiated. More importantly, they simply fly in the face of the "on the ground" decisions made by alfalfa growers who are free to buy whatever products they think are in their best interests. These growers have provided the best evidence available that there are substantial advantages to RRA forage—they have been buying it at an unusually fast clip.

Summary of Conclusions

52. On March 23, 2007, I filed a report that presented the results of my analysis of the economic impact on the members of the RRA supply chain of an injunction during the time of the EIS with respect to RRA. I found that the economic impact of such

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[13] The premium cost of RRA seed of $3 per pound extended to 18 pounds planted by the forage grower per acre leads to a premium RRA seed cost of $54 per acre. An acre of planted seed yields forage harvests for four to six years before it needs to be replaced. Therefore, the $3 per pound premium cost of RRA seed amounts to between a $9 per acre per year premium ($54 per acre for 18 pounds divided by six years of harvesting) to a $13.50 per acre per year premium ($54 per acre for 18 pounds divided by four years of harvesting).

an injunction would be, approximately, a lost contribution margin (lost profits) of $225 million, net of all reasonable mitigation offsets throughout the supply chain.

53. On April 6, 2007, plaintiffs filed a response to Intervenors' Memorandum Regarding Permanent Relief, dated March 23, 2007. This response from plaintiffs made reference to a number of declarations provided by various parties associated with the plaintiffs, as well as a declaration from Charles M. Benbrook, PhD and Chief Scientist at the Organic Center.

54. I was asked by the intervenors to:

- comment on the relevance of the claims made in various plaintiff declarations with respect to the question of the economic impact on the plaintiffs of no injunction during the time of the EIS study,
- comment on the relevance of Dr. Benbrook's claims regarding the economic impact on the plaintiffs of no injunction during the time of the EIS study, and
- respond to Dr. Benbrook's critique of my March 23, 2007 report.

55. I have now responded as follows:

- the plaintiffs' declarations did not really speak to the question of how they would be impacted by the absence of an RRA injunction during the time it takes to complete the EIS in that they did not estimate how their profits, net of reasonable mitigation offsets, would be impacted specifically by the absence of an RRA injunction just during the time it takes to complete the EIS

- neither did Dr. Benbrook speak to the question of how the plaintiffs would be impacted by the absence of an RRA injunction during the time it takes to complete the EIS in that he did not estimate how plaintiffs' profits, net of reasonable mitigation offsets, would be impacted specifically by the absence of an RRA injunction just during the time it takes to complete the EIS
- Dr. Benbrook's critique of my estimated $225 million as the negative economic impact on the intervenors from an RRA injunction during the time it takes to complete the EIS is misplaced in every respect.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 20th day of April 2007 At Minneapolis, Minnesota.

/s/
TIMOTHY J. NANTELL

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/
B. ANDREW BROWN

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA -
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al., Plaintiffs, v. MIKE JOHANNS, Secretary of the United States Department of Agriculture, et al., Defendants, and JOHN GROVER, DANIEL MEDEROS, MARK WATTE, FORAGE GENETICS, INC., and MONSANTO COMPANY, Intervenor-Defendants.	NO. C-06-01075 CRB REBUTTAL TESTIMONY OF BOB HAMMON DATE: April 27, 2007 TIME: 11:00 A.M. DEPT: Courtroom 8, 19th Floor Judge: The Honorable Charles R. Breyer

Q. PLEASE STATE YOUR NAME AND BUSINESS ADDRESS.

A. My name is Bob Hammon. My business address is 2775 Highway 50, P.O. Box 20,000-5028, Grand Junction, Colorado 81502-5028.

Q. WHO IS YOUR EMPLOYER AND WHAT IS YOUR POSITION?

A. I am employed as an extension agent specializing in entomology and agronomy at the Colorado State University Cooperative Extension. I cover an area in western Colorado comprised of four counties:

Mesa County, Delta County, Montrose County, and Ouray County.

Q. WHAT ARE YOUR QUALIFICATIONS AND EXPERIENCE?

A. I received a B.S. in Natural Resources from the University of Michigan in 1975 and a M.S. in Entomology from Colorado State University in 1988. I was employed by Michigan Cooperative Extension from 1976 to 1979 and by the Colorado Agricultural Experiment Station from 1988-2003. I have been at my current position since 2003. My specialty is management of agricultural pests. I have worked with local alfalfa seed growers conducting entomology research for the past ten years.

Q. DID YOU PREPARE THE STUDY "POLLEN MOVEMENT FROM ALFALFA SEED PRODUCTION FIELDS"?

A. Yes. This research was sponsored by Forage Genetics and conducted in cooperation with Waters Farms, Fruita Colorado. The final report from this 2006 project was presented at the annual meeting of the Northwest Alfalfa Seed Growers Association in Las Vegas, Nevada on January 22, 2007, and is posted on my web site for public access. See http://wci.colostate.edu/agriculture.html.

Q. WHAT WAS THE PURPOSE OF THE STUDY?

A. I conducted research on pollen movement from Roundup Ready alfalfa fields by alkali bees in 2006. The purpose of the study was to measure the distance Roundup Ready pollen moved from Roundup Ready seed production fields to feral plants within two miles of active Roundup Ready alfalfa seed fields in Mesa County. The study also

estimated the role alkali bees play in alfalfa pollen transport from Roundup Ready seed production fields to feral alfalfa. Finally, the study determined which bee species were active in moving Roundup Ready pollen from seed production fields to feral alfalfa.

Q. HAVE YOU READ THE DECLARATIONS OF ALLISON SNOW, DOUG GURIAN-SHERMAN, ERNEST JOHNSON, JOHN MARKEGARD, JIM BRIGGS, AND PHILLIP GEERTSON RECENTLY FILED IN THIS CASE?

A. Yes, I have read the parts of those declarations relating to my "Pollen Movement" study.

Q. IN THOSE DECLARATIONS, THE DECLARANTS STATE THAT YOUR STUDY SHOWS THAT HIGH LEVELS OF GENE FLOW FROM ROUNDUP READY ALFALFA SEED FIELDS OCCUR AT DISTANCES THAT COULD MAKE CURRENT ISOLATION DISTANCES BETWEEN ROUNDUP READY ALFALFA SEED FIELDS AND NON-ROUNDUP READY FIELDS INADEQUATE. ARE YOU FAMILIAR WITH THOSE STATEMENTS?

A. Yes.

Q. DO YOU HAVE ANY COMMENTS REGARDING HOW THESE DECLARANTS REPRESENT AND RELY ON THE CONCLUSIONS OF YOUR STUDY?

A. My research was not designed to provide a basis to estimate pollen flow from Roundup Ready alfalfa seed fields to conventional seed production fields. The use of my data for this purpose is scientifically unsound. The declarants suggest that this data

shows that bees are capable of contaminating non-Roundup Ready alfalfa seed production fields at levels equal to the 3.78% at 1.7 miles. This is not true. This data is taken out of context, and does not reflect my analysis of the results. My study did not involve a receiving site (known as a "trap") that was a conventional seed production field. This is a critical distinction. At the receiving site in question, we collected about 400 seeds from about a dozen alfalfa plants in an abandoned alfalfa field. The data suggests that the Roundup Ready alfalfa seed recovered from this site was the result of very few bee visits. Due to the inevitable dilution effect, the same number of bee visits in a multiple acre seed production field with 20,000 plants per acre would result in a very low contamination level. Under such circumstances, finding the presence of the Roundup Ready alfalfa seed in a conventional seed field would have been like finding a needle in a haystack. My experiment was not designed to estimate potential pollen flow from one seed field to another seed field. Other scientists such as Larry Teuber and Sharie Fitzpatrick have in fact conducted and reported on such studies, as I mentioned in my report "Feral Alfalfa Plants and Pollen-Mediated Gene Flow in Alfalfa" offered with the Second Declaration of Mark H. McCaslin.

Q. IN THE DECLARATION OF ERNEST JOHNSON, MR. JOHNSON STATES THAT AT THE NORTHWEST SEED GROWERS MEETING IN LAS VEGAS ON JANUARY 22-23, 2007, HE ASKED YOU "HOW FAR [YOU] WOULD SAY THAT A FIELD WOULD HAVE TO BE AWAY FROM A ROUNDUP READY

FIELD AND NOT BE POTENTIALLY CONTAMINATED?" MR. JOHNSON STATES THAT YOUR RESPONSE WAS FIVE MILES. ARE YOU FAMILIAR WITH THIS STATEMENT IN MR. JOHNSON'S DECLARATION?

A. Yes.

Q. DID MR. JOHNSON ACCURATELY AND COMPLETELY REPORT ON YOUR STATEMENT?

A. No. Mr. Johnson reported my statement out of context. I presented the results of my "Pollen Movement" study at the Northwest Seed Growers Association meeting in Las Vegas, Nevada in January 2007. At that conference, I discussed isolation distances from Roundup Ready alfalfa seed fields to conventional seed fields with several individuals, including Mr. Johnson. I stated my opinion that in order for there to be zero tolerance of any gene flow between a Roundup Ready alfalfa seed field and a conventional seed field, those fields would have to have a five-mile isolation distance between them. But I have not conducted any research or prepared any analysis to support this estimate. My "Pollen Movement" study certainly does not provide a basis for setting five-mile isolation distances between seed fields.

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct. Executed this 16th day of April 2007 at Grand Junction, Colorado.

/s/
BOB HAMMON

Attorney Signature Attestation

I, B. Andrew Brown, counsel for Forage Genetics, Inc., hereby attest that I have on file all holographic signatures for any signatures indicated by a "conformed" signature (/s/) within this enfiled documents.

/s/
B. ANDREW BROWN

[1] UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
BEFORE THE HONORABLE CHARLES R. BREYER

GEERTSON SEED FARMS, *ET AL.*	)	
PLAINTIFFS,	)	
V.	)	No. C 06-1075 CRB
MIKE JOHANNS, SECRETARY OF THE UNITED STATES DEPARTMENT OF AGRICULTURE, ET AL.	)	SAN FRANCISCO, CALIFORNIA FRIDAY, APRIL 27, 2007
DEFENDANTS.	)	

TRANSCRIPT OF PROCEEDINGS

* * *

[8] JUST ONE NOTE ON THE NUMBER OF ACRES. MR. MCCASLIN'S TESTIMONY SAYS 19,000 ACRES, NOT 20,000 ACRES, JUST—

THE COURT: SO IT'S A SMALLER PROBLEM.

MR: ROSTOV: SMALLER PROBLEM. AND, ACTUALLY, THEY ORIGINALLY HAD 75 AND SOMEHOW FOUND ANOTHER FIVE.

THE COURT: I DON'T KNOW THAT THAT MAKES ANY MEANINGFUL DIFFERENCE.

I THINK FIRST I SHOULD ASK THE GOVERNMENT—I DON'T KNOW WHETHER IT'S

THE GOVERNMENT OR FORAGE—TO TELL US—THE GOVERNMENT HAS SUGGESTED A NUMBER OF MEASURES THAT COULD BE TAKEN IN CONNECTION WITH THE DISSEMINATION OF THE SEED. ARE THESE MEASURES PRESENTLY REQUIRED IN THE CONTRACTS THAT MONSANTO AND FORAGE HAVE, OR ARE THEY NEW MEASURES, IF YOU KNOW, AND MAYBE YOU MIGHT NOT KNOW?

MR: PAGE: YOUR HONOR, THAT QUESTION, I BELIEVE, IS ADDRESSED IN THE SECOND DECLARATION OF NEIL HOFFMAN THAT WAS FILED MARCH 7TH, BUT I CAN SAY THAT SOME OF THE CONDITIONS, SOME OF THE SIX MANDATORY ENVIRONMENTAL MITIGATION CONDITIONS THAT WOULD BE IMPOSED IN THE APHIS' PROPOSED JUDGMENT HAVE BEEN PART OF THE CONTRACTUAL RELATIONSHIP BETWEEN AND AMONG GROWERS. HOWEVER, SOME OF THEM ARE MORE STRINGENT, AND THE DIFFERENCE IS IS THAT THEY WOULD HAVE THE FORCE OF THE PLANNED PROTECTION ACT BEHIND THEM.

AS THE COURT MIGHT HAVE GLEANED FROM THE MOST RECENT [9] PROPOSED JUDGMENT SUBMITTED BY APHIS, WHICH IS ATTACHMENT B TO THE SECOND DECLARATION OF DR. HOFFMAN, THE MECHANISM WOULD BE AN ADMINISTRATIVE ORDER UNDER THE PLANT PROTECTION ACT THAT WOULD BE SPECIFIC TO MONSANTO AND FORAGE GENETICS AND THE CORRESPONDING REQUIREMENT THAT

ALL OF THE HAY PRODUCERS AND SEED PRODUCERS WOULD CONTRACT SOLELY WITH THOSE TWO ENTITIES.

THE COURT: OKAY. THANK YOU.

YES, COUNSEL?

MS: SCHNEIDER: YOUR HONOR, WE CONCUR WITH THE GOVERNMENT'S REPRESENTATIONS.

AND, ALSO, FOR YOUR INFORMATION, ALL OF THE FARMERS WHO USE ROUNDUP READY ALFALFA ARE LICENSED DIRECTLY TO MONSANTO.

THE COURT: NOW, WHILE I HAVE YOU UP HERE, LET ME GET TO THE HEART OF IT.

FIRST OF ALL, I'VE READ THE DECLARATIONS. I APPRECIATE THAT THIS COULD HAVE BEEN THE SUBJECT OF LIVE TESTIMONY, BUT I THOUGHT THE DECLARATIONS WERE CERTAINLY COMPREHENSIVE IN STATING THE FACTS AS THE DECLARANT KNEW THEM TO BE.

BUT I THINK THERE'S A DIFFERENT QUESTION, AND THE QUESTION I THINK IS THE SIGNIFICANT QUESTION IS WHETHER OR NOT THERE SHOULD BE ANY INCREASE IN THE RISK OF FURTHER CONTAMINATION WITHOUT THE BENEFIT OF THE ENVIRONMENTAL IMPACT STATEMENT WHICH HAS BEEN ORDERED BY THE COURT IN COMPLIANCE [10] WITH THE FINDINGS OF THE COURT AND TO WHICH THE GOVERNMENT HAS AGREED, AS I UNDERSTAND THE PLEADINGS, TO PERFORM.

SO IN THAT REGARD, MY QUESTION IS, IS THERE A SINGLE CASE OUT THERE THAT YOU CAN POINT TO THAT RESULTED, PENDING THE STUDY THAT WAS TO BE DONE OR ORDERED BY THE COURT, IN AN INCREASE IN THE EXPOSURE OR THE USE OF THE PARTICULAR QUANTITY OR THE INCREASE IN THE ITEM THAT'S UNDER INVESTIGATION?

I UNDERSTAND THAT THERE HAVE BEEN CASES WHICH HAVE ALLOWED, FOR EXAMPLE, CATTLE TO CONTINUE TO GRAZE OR, IN A CASE OUT OF THIS COURT WITH JUDGE LAPORTE, ALLOWING TRAILS TO BE—YOU KNOW, WALKING IN PARKS AND SO FORTH, OR FORESTS, TO BE ALLOWED TO CONTINUE DURING THE COURSE OF THE STUDY.

AND, INDEED, MY VIEW—MY ORDER ALLOWED ALL THOSE ITEMS, ALL THE SEED THAT HAD BEEN PLANTED, TO BE—TO CONTINUE TO BE PRODUCTIVE.

BUT I HAVEN'T FOUND A SINGLE CASE, A SINGLE CASE THAT HAS SAID, WELL, DURING THIS PROCESS, FINDING WHAT YOU FOUND, YOU CAN NOW INCREASE THE AMOUNT. IS THERE SUCH A CASE, AND WHAT WOULD THAT BE?

MS: SCHNEIDER: WELL, YOUR HONOR, I THINK THERE ARE A COUPLE OF THINGS TO THINK ABOUT WHEN YOU LOOK AT THAT QUESTION.

THE COURT: WELL, THE WAY I REALLY WANT TO START TO LOOK AT IT IS I WANT A

CASE CITATION. THAT'S THE WAY I WOULD LIKE TO START MY INQUIRY. IS THERE A CASE YOU CAN CITE TO ME [11] THAT WOULD STAND FOR THE PROPOSITION AS I ARTICULATED IT, THAT IS, THAT YOU CAN INCREASE THE USE OF THE PRODUCT WHICH IS SUBJECT TO THE STUDY OF THE TYPE THAT I'VE ORDERED AND WHICH THE GOVERNMENT HAS AGREED TO CONDUCT?

MS: SCHNEIDER: YOUR HONOR, THE CASE THAT I WOULD DIRECT YOU TO WOULD BE THE BORDER POWER PLANT WORKING GROUP CASE.

I THINK THE WAY THEY WOULD HAVE TO LOOK AT THIS ISSUE IS NOT A QUESTION OF WHETHER THERE'S AN INCREASE IN ACREAGE OF ROUNDUP READY ALFALFA, BUT, RATHER, WHETHER AN ONGOING ACTIVITY THAT IS PERMITTED TO CONTINUE DURING THE TIME THAT THE ENVIRONMENTAL ASSESSMENT/ ENVIRONMENTAL IMPACT STATEMENT IS BEING CONDUCTED HAS ANY SORT OF ENVIRONMENTAL HARM.

IN THAT CASE WHICH JUDGE GONZALEZ IN THE SOUTHERN DISTRICT OF CALIFORNIA ISSUED, THERE WAS NO QUESTION THAT OPERATION OF THE POWER PLANT DURING THE INTERIM PERIOD OF TIME WOULD HAVE CONTINUING AND ONGOING ENVIRONMENTAL EFFECTS, AND I WOULD PROFFER TO YOU THAT IS REALLY AN ADDITION TO THE ENVIRONMENT OF A PARTICULAR ENVIRONMENTAL IMPACT

THAT WAS AT SPECIFIC ISSUE IN THAT CASE, BECAUSE THE QUESTION OF AIR POLLUTION AND THE EFFECTS OF AIR POLLUTION ON HUMAN HEALTH, PARTICULARLY IN IMPERIAL COUNTY WHERE ASTHMA IS VERY SEVERE, YOU KNOW, WAS THE KEY ISSUE IN THE CASE.

SO I THINK THE WAY YOU HAVE TO LOOK AT THIS QUESTION [12] IS NOT STRICTLY A QUESTION OF, WELL, IF I ADD ANOTHER ACRE OR ANOTHER TEN THOUSAND ACRES, DOES THAT INCREASE THE RISK.

THE COURT: IF A PLANT WAS SHUT DOWN IN THAT CASE, IF THE PLANT WERE SHUT DOWN IN THAT CASE, WHICH IT WASN'T, THAT WOULD BE—BUT THE ENVIRONMENTALISTS PROBABLY WANTED IT TO BE SHUT DOWN.

MS: SCHNEIDER: THAT'S CORRECT. THEY ASKED FOR AN INJUNCTION, AND JUDGE GONZALEZ DENIED IT.

THE COURT: RIGHT.

BUT IF IT HAD BEEN GRANTED THAT THEN WOULD HAVE RESULTED IN A REDUCTION, WOULD IT NOT, OF THE POLLUTANTS WHICH WERE CLAIMED TO HAVE BEEN AT ISSUE IN THAT CASE, AND THERE WOULD HAVE BEEN— THAT'S ON THE POSITIVE SIDE. ON THE NEGATIVE SIDE WOULD HAVE BEEN A DIMINUTION OF THE POWER AVAILABLE, I GUESS—IT'S A POWER PLANT, ISN'T IT?

MS: SCHNEIDER: THAT'S CORRECT.

THE COURT: THE POWER AVAILABLE TO SERVE THE COMMUNITY.

MS: SCHNEIDER: WELL, THERE WOULD HAVE BEEN—AS I THINK IS ANALOGOUS IN THIS CASE, THERE WOULD HAVE BEEN DIFFERENT KINDS OF ENVIRONMENTAL IMPACTS. IN THAT CASE WHAT WOULD HAVE HAPPENED IF THE POWER PLANT WERE SHUT DOWN, IS THAT, SINCE THERE WAS AN ONGOING POWER NEED, OTHER PLANTS, WHICH WERE DIRTIER PLANTS, BECAUSE THEY DIDN'T HAVE THE STATE OF THE ART TECHNOLOGY THAT THE PLANT AT ISSUE IN THE LITIGATION HAD, WOULD [13] HAVE STEPPED UP, AND THERE WOULD HAVE BEEN MORE ENVIRONMENTAL IMPACTS HERE.

VERY SIMILARLY, IN OUR CASE, THERE ARE SOME SIGNIFICANT ENVIRONMENTAL AND SOCIETAL BENEFITS TO ALLOWING THE USE OF ROUNDUP READY ALFALFA THOSE INCLUDE.

THE COURT: YOU CAN'T ARGUE YOUR RESULT. SEE, THE PROBLEM IS—YES, I'M NOT SAYING, AND I HAVEN'T SAID, THAT ROUNDUP READY ALFALFA MIGHT BE THE GREATEST THING SINCE PENICILLIN. I DON'T KNOW. I DON'T THINK IT IS, AND I DON'T THINK YOU ARE CLAIMING THAT. I DON'T KNOW. I DON'T KNOW.

AND THEN I FAULT TO THE GOVERNMENT AGAIN FOR NOT KNOWING ITS BENEFICIAL EFFECTS, BUT NOT STUDYING THE ENVIRONMENTAL IMPACT IT COULD HAVE.

THAT'S WHAT I FAULTED THE GOVERNMENT WITH HAVING DONE.

SO I'M NOT AN ENVIRONMENTAL AGENCY. I'M NOT THE PERSON WHO HAS TO LOOK AND ANALYZE AND TRY TO FIGURE OUT, DOES THIS HAVE AN ENVIRONMENTAL IMPACT OR DOESN'T IT, YOU KNOW, AND ALL THE MEASURES AND SO FORTH. WE ALLOW THE GOVERNMENT IN THE FIRST INSTANCE TO DO THAT.

IT JUST SEEMS TO ME THAT EVERYTHING THAT YOU'VE PRESENTED TO ME, WITH DUE RESPECT, ESSENTIALLY IS THE ARGUMENT THAT I COULD BE LIKE A SUPER ENVIRONMENTAL AGENCY ENGAGED IN BALANCING ALL OF THESE DIFFERENT FACTORS AND COMING TO PARTICULAR CONCLUSIONS, WHICH I FEEL PARTICULARLY ILL SUITED TO DO, NUMBER ONE. AND, NUMBER TWO, IT ISN'T MY JOB. IT DIDN'T [14] COME WITH MY JOB DESCRIPTION. IT CAME WITH THE JOB DESCRIPTION OF THE GOVERNMENT OF THE UNITED STATES. CONGRESS TOLD THE GOVERNMENT TO DO THIS, THE EXECUTIVE BRANCH TO DO IT, NOT THE JUDICIAL BRANCH.

AND SO YOUR ARGUMENTS, FOR THE MOST PART, AS I HAVE INTERPRETED THEM HAVE REALLY—AT ITS BASE LEVEL HAVE SUGGESTED TO ME THAT I OUGHT TO BE ENGAGED IN THIS PROCESS THAT I'M PERFECTLY CAPABLE OF DOING. I DON'T KNOW WHETHER I AM OR NOT, BUT HAVING FOUND THAT IT OUGHT TO BE THE

GOVERNMENT THAT DOES IT, I THOUGHT MY CASE IS VERY SIMPLE WHAT I SHOULD DO.

I SHOULD MAKE SURE THAT THE HARM, IF THERE IS HARM, DOESN'T INCREASE. I SHOULD STOP THINGS IN ITS PLACE UNTIL THE GOVERNMENT HAS DISCHARGED ITS DUTY GIVEN TO IT BY THE RIGHT OF CONGRESS OF THE UNITED STATES.

ONCE THAT'S DONE, THEN WHATEVER THOSE CONCLUSIONS ARE AND WHATEVER THE BASIS IS, THEN IT'S OUT THERE. IT'S BEEN STUDIED, AND IT'S BEEN RELEASED.

AND BUT—BUT FOR YOU TO COME IN, AND I MEAN THIS DEFERENTIALLY, BECAUSE I MEAN I DON'T—I'M NOT ACCUSING YOU—I'M SAYING FOR A PARTY TO COME IN AND SAY, WELL, LOOK, JUDGE, WE THINK THAT YOU OUGHT TO INCREASE THE USE OF THIS PRODUCT PENDING THE DETERMINATION BECAUSE WE'RE SURE IT'S SAFE, AND, BY THE WAY, WE'RE SURE THAT—NOT JUST SAFE, WE'RE SURE THAT IT WON'T RESULT IN THE DESTRUCTION OF BIODIVERSITY, THAT WE ARE SURE THAT IT CAN BE CONTROLLED IN A WAY THAT IT WON'T

* * *

THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS, et al.,	) NO. C-06-01075 CRB
Plaintiffs,	) DECLARATION OF NAONORI OISHIS IN SUPPORT OF
vs.	) PLAINTIFFS' OPPOSITION TO
MIKE JOHANNS, et al.,	) DEFENDANTS' MOTION TO
Defendants.	) APPROVE APHIS' PROPOSED JUDGMENT

I, Naonori Oishi, do hereby declare as follows:

1. I have personal knowledge of the following and could competently testify if called as a witness.

2. I am the Manager of Acquisition for Sekido & Co., Inc, a specialty import company of feed products in Japan. I have been involved in the hay importation business for 18 years.

3. Sekido & Co. imports approximately 15,000 tons of alfalfa hay and 50,000 tons of other hay per year from U.S. farmers. All of our feed imports are genetically modified organism (GMO) free. We do not import any Roundup Ready alfalfa because there is virtually no market in Japan for GMO alfalfa.

4. While the Japanese government has legally approved the sale of Round Up-ready alfalfa, the

Japanese market does not want Roundup Ready alfalfa at this moment.

5. Most importers in Japan do not want Roundup Ready alfalfa in the market because it increases the cost of doing business due to the need to segregate Roundup Ready alfalfa from non-genetically engineered alfalfa.

6. Imported alfalfa is primarily used for feed for cattle in the dairy industry. The vast majority of Japanese consumers reject products with Genetically Modified Organisms (GMO) because of food safety concerns. In particular, the Japanese consumer does not want milk that is produced with GMO alfalfa because children consume most of the milk in Japan, and Japanese consumers are especially sensitive about giving foods with GMOs to children.

7. There is virtually no market for Roundup Ready alfalfa in Japan, and it would be very difficult to sell Roundup Ready alfalfa to Japanese importers and consumers because the end user does not accept foods with GMOs at this time.

Executed on March 6, 2007, in San Francisco, CA

/s/

Naonori Oishi

I, William Rostov, hereby attest that I have on file all holograph signatures for any signatures indicated by a "conformed" signature (/S/) within this e-filed document.

[1] UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEERTSON SEED FARMS,)
) Case No. C06-1075 CRB
PLAINTIFFS,
) JUNE 22, 2007
VERSUS
) SAN FRANCISCO,
MIKE JOHANNS,
) CALIFORNIA
DEFENDANTS.
_____)

BEFORE THE HONORABLE CHARLES R. BREYER

UNITED STATES DISTRICT COURT JUDGE

* * *

[15] IT WITH FARMERS WHO HAVE AN INTEREST, AS THE COURT DESCRIBED, IN ASCERTAINING WHETHER THEIR CROPS SHOULD BE TESTED OR NOT FOR GENETIC AGENTS.

THE COURT: SO YOUR POINT IS IT OUGHT TO BE BROADER.

MR. PAGE: YES, EXACTLY.

THE COURT: I SORT OF—HERE IS MY TENTATIVE VIEW ON IT. MY TENTATIVE

VIEW WOULD BE TO ALLOW THEM TO SET IT UP THIS WAY. IF IT TURNS OUT THAT IT'S NOT WORKING, IT TURNS OUT THAT YOU HAVE SOME CONCERNS AS TO THE AVAILABILITY OF THIS INFORMATION, THAT IT'S SOMEHOW BEING UNDULY RESTRICTED, THEN, OF COURSE, THESE CAN BE MODIFIED. I ASSUME I CAN MODIFY IT AT ANY TIME. I THINK I DO, EVEN THOUGH IT MAY BE APPEALED—i THINK I DO RETAIN JURISDICTION TO ENTERTAIN ANY SORT OF MODIFICATION OF IF IT TURNS OUT THAT IT'S NOT WORKING.

IT'S MY SENSE WE OUGHT TO SEE IF IT WORKS. WE OUGHT TO GIVE PEOPLE A CHANCE TO SEE IF IT WORKS AFTER A MAIN RELIEF IS PUT IN PLACE. THIS IS SOMEWHAT ANCILLARY, THOUGH I DON'T SAY IT'S NOT SIGNIFICANT.

I'D LIKE TO SEE WHETHER THE MEASURES WHICH I THINK THE GOVERNMENT IS PROPOSING HERE ACTUALLY WORKS. IF NOT—IF IT WORKS, IT'S NOT A PROBLEM. IF IT DOESN'T, WE ADDRESS IT. I'M HERE. I'M NOT GOING ANYWHERE, AT LEAST I DON'T THINK SO. SO I WOULD HEAR ON SHORT NOTICE ANY REQUEST FOR MODIFICATION OR ANY CONCERNS THAT ARE ADDRESSED. I WOULD BE HERE FOR THAT.

MR. PAGE: I GUESS THERE IS AN ISSUE OF DEFINITION IN

* * *

[26] THE OTHER ISSUE THAT PLAINTIFFS HAVE MENTIONED TWICE IS THE ISSUE UNDER RULE 59(H), WHETHER THE GOVERNMENT COULD HAVE REALISTICALLY RESPONDED TO PLAINTIFF'S PUBLIC—

THE COURT: I ACTUALLY THINK THIS IS AN EVOLVING SITUATION; THAT CERTAIN REMEDIES WERE SUGGESTED BY THE GOVERNMENT WHICH I IMPLEMENTED, I THINK, TO A LARGE MEASURE. BUT IT'S IN THE CONTEXT OF WHERE WE ARE TODAY AND I AM—NOT ALL, BUT SOME OF THE CONCERNS RAISED BY THE GOVERNMENT, I THINK ARE APPROPRIATE TO SEEING HOW WE GO FORWARD AT THIS POINT. YOU COME IN, YOU SAY, "LOOK, WE ARE GOING TO DO THIS STUDY, WE'RE FOLLOWING THE COURT'S DISCRETION IN THAT REGARD," AND THAT'S THE MOST SIGNIFICANT THING THAT I LOOK AT. SO I'M TRYING TO FASHION A REMEDY THAT I THINK WILL ACCOMODATE EVERYONE'S PRESENT CONCERNS.

OBVIOUSLY, IF SOMETHING WAS SAID TODAY AND NOT SAID YESTERDAY, ONE WONDERS WHY IT WASN'T SAID YESTERDAY. THERE ARE EXPLANATIONS TO SOME EXTENT, MAYBE NOT. I WILL WEIGH IT ALL.

MR. PAGE: THE FINAL POINT IS THIS: IF THE PARTIES ARE DEBATING ABOUT THE COMPREHENSIVENESS OF THE TERM "FARMER" IN OPERATING THE WEBSITE ON THE BASIS, PARTIALLY, ON A PARTICULAR FARMERS'S REQUEST, THE GOVERNMENT WOULD JUST LIKE TO POINT OUT THAT THE

COURT'S REFERENCE TO A FARMER'S NEED TO ASCERTAIN, TO RECEIVE THE INFORMATION NECESSARY TO ASCERTAIN WHETHER TO TEST OR NOT TEST THE CROPS, BY THE GOVERNMENT'S DECISION TO OPERATE THE WEBSITE ON THE BASIS OF WHETHER IT'S A FARMER REQUESTING,

* * *

PETITIONER'S BRIEF

Supreme Court, U.S.
FILED
MAR - 1 2010
OFFICE OF THE CLERK

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
Petitioners,
v.
GEERTSON SEED FARMS, ET AL.,
Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

In this case, after finding a violation of the National Environmental Policy Act ("NEPA"), the district court imposed, and the Ninth Circuit affirmed, a permanent nationwide injunction against any further planting of a valuable genetically engineered crop, despite overwhelming evidence that less restrictive measures proposed by an expert federal agency would eliminate any non-trivial risk of harm. The questions presented are:

1. Whether the Ninth Circuit erred in holding that NEPA plaintiffs are specially exempt from the requirement of showing a likelihood of irreparable harm to obtain an injunction.

2. Whether the Ninth Circuit erred in holding that a district court may enter an injunction sought to remedy a NEPA violation without conducting an evidentiary hearing sought by a party to resolve genuinely disputed facts directly relevant to the appropriate scope of the requested injunction.

3. Whether the Ninth Circuit erred when it affirmed a nationwide injunction entered prior to this Court's decision in *Winter v. NRDC*, 129 S. Ct. 365 (2008), which sought to remedy a NEPA violation based on only a remote possibility of reparable harm.

PARTIES TO THE PROCEEDING

In the United States Court of Appeals for the Ninth Circuit, the plaintiff-appellees were Geertson Seed Farms, Trask Family Seeds, Center for Food Safety, Beyond Pesticides, Cornucopia Institute, Dakota Resource Council, National Family Farm Coalition, Sierra Club, and Western Organization of Resource Councils. The defendant-appellants were Mike Johanns (in his official capacity as Secretary of the U.S. Department of Agriculture), Ron Dehaven (in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture) and Steve Johnson (in his official capacity as Administrator of the U.S. Environmental Protection Agency). The intervenor-defendant-appellants were Monsanto Company, Forage Genetics International, LLC, John Grover, Daniel Mederos, and Mark Watte. John Grover is not a party to this appeal.

Pursuant to Supreme Court Rules 24.1 and 29.6, there is no change to the corporate disclosure statement previously filed by petitioners.

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The district court's opinion is unpublished and reproduced at Pet.App.60a-79a. The Ninth Circuit's original and amended opinions are reported at 541 F.3d 938, and 570 F.3d 1130, and reproduced at Pet.App.80a-103a and Pet.App.1a-26a, respectively.

JURISDICTION

The Ninth Circuit vacated its original opinion, entered an amended judgment, and denied a petition for rehearing and rehearing en banc on June 24, 2009. Pet.App.104a-07a. After Justice Kennedy extended the time for filing petitions for certiorari, petitioners filed a timely petition on October 22, 2009. This Court granted certiorari on January 15, 2010. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL, STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent constitutional, statutory, and regulatory provisions are reproduced in the addendum and at Pet.App.115a-19a.

STATEMENT OF THE CASE

Since the dawn of agriculture, mankind has grown different varieties of the same crops and maintained their varietal purity. A stroll down the aisles of any supermarket in America illustrates that today's farmers are capable of growing an array of distinct crop varieties despite the potential for cross-pollination among different types. Farmers successfully grow sweet corn despite its ability to cross-pollinate with field corn and popcorn, green cabbage despite its compatibility with red cabbage, and different compatible varieties of onions, radishes, chard, beets, and so on. The ability to grow distinct varieties while

maintaining varietal purity is accomplished by well-established stewardship techniques, including isolation distances between crops.

In recent decades, genetically engineered crops have become a mainstay of American agriculture because of their enormous benefits, including higher yields, disease and insect resistance, their compatibility with less toxic pesticides, lower operating costs, and increased farm income. As of 2009, farmers had planted genetically engineered varieties on 91% of soybean, 85% of corn, 88% of cotton, and over 90% of sugarbeet acres grown in the United States.[1] Just like growers of conventional varieties, farmers of genetically engineered crops have used isolation distances and other traditional stewardship measures successfully to address cross-pollination with conventional and organic crops.[2]

In this case, respondents successfully challenged under the National Environmental Policy Act ("NEPA") the procedures the federal government followed when it approved the planting and sale of a genetically engineered alfalfa variety known as Roundup Ready alfalfa ("RRA"). Before the district court's judgment, farmers had planted RRA for 21 months without *any* judicially or governmentally imposed restrictions—and demonstrated that they knew how to be good stewards. It is undisputed that

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[1] Pet.App.258a-59a; ERS, USDA, Data Sets, *Adoption of Genetically Engineered Crop in the U.S.: Extent of Adoption*, http://www.ers.usda.gov/Data/BiotechCrops/adoption.htm.

[2] "Cross-pollination" is used synonymously in this brief with cross-fertilization or "gene flow," to indicate not just that pollen is exchanged, but that the exchange results in viable seed or new plants.

this variety of alfalfa is perfectly safe for human and animal consumption. Pet.App.43a. There is no evidence that there was *any* cross-pollination between RRA and conventional or organic varieties in the 22 million acres of alfalfa grown for hay (which account for 99% of alfalfa acreage in the United States). There is no evidence that *any* farmer lost *even a single* sale of conventional or organic hay or seed because of "contamination" with genetically engineered alfalfa. And even respondents[3] conceded that sufficiently protective isolation distances would prevent any cross-pollination between RRA and organic or conventional alfalfa. Cert. Opp. at 9 n.6.

Nevertheless, seizing on science fiction-like scenarios that RRA would cause the extinction of *all* non-RRA alfalfa crops, respondents sought to enjoin the planting of all RRA in the United States. After finding that the government violated NEPA's procedural requirements, the district court entered a nationwide injunction banning the new planting of genetically engineered alfalfa regardless of its proximity to other crops. The court rejected out of hand the tailored injunction proposed by the expert federal agency charged with overseeing genetically engineered crops, which would have mandated isolation distances and other stewardship measures to avoid cross-pollination. Indeed, the court refused to engage in any serious inquiry into the likelihood of RRA causing irreparable harm in the absence of a blanket injunction—and thus refused to conduct an evidentiary hearing on that issue at all. Instead, the court stood on its view that an injunction is warranted "'[i]n the run of

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[3] As used herein, "respondents" refers to plaintiffs below, and not to the governmental respondents supporting petitioners.

the mill NEPA case ... until the NEPA violation is cured.'" Pet.App.55a, 65a-66a (citation omitted).

The Ninth Circuit affirmed the blanket nationwide injunction in all respects. In so ruling, the court disregarded this Court's teachings—reiterated just last Term in *Winter v. NRDC*, 129 S. Ct. 365 (2008)—that an injunction is an "extraordinary remedy" that may be granted only when necessary to prevent likely irreparable harm. *Id.* at 376. And the Ninth Circuit compounded that error by affirming the district court's rejection of petitioners' request for an evidentiary hearing on the potential for irreparable harm—in conflict with centuries of common law, basic concepts of due process, the Federal Rules of Civil Procedure, and the vast weight of precedent. The judgment of the Ninth Circuit should be reversed.

BACKGROUND

1. Conventional Alfalfa

Alfalfa—known as the "Queen of the Forages"—is one of the oldest cultivated plants in recorded history and is today the most cultivated legume in the world. It is a perennial crop with a three- to five-year productive lifespan. Pet.App.126a. Each year, over 22 million acres of alfalfa are grown in the United States—making alfalfa the fourth most widely grown crop in the nation (behind corn, wheat, and soybeans). Pet.App.27a, 330a. Ninety-nine percent of alfalfa is grown to produce hay, which is used primarily as feed for livestock. Pet.App.126a, 321a-22a, 330a.

Alfalfa varieties cannot cross-pollinate unless pollen moves from one variety of an alfalfa plant to another variety while both fields are flowering. Hay crops are harvested by mowing the alfalfa fields at regular intervals, however, before the flowers open and

produce the pollen necessary for cross-pollination. Pet.App.126a, 225a.

The remaining 1% of alfalfa acreage is devoted to seed production and is concentrated largely in eight western states. Pet.App.313a, 322a, 380a. Unlike hay crops, seed crops are deliberately permitted to complete alfalfa's life-cycle—*i.e.*, the plants are permitted to flower to create the pollen that can be carried to another flowering plant to generate new seeds. Because alfalfa does not shed pollen to the wind, Pet.App.129a, 230a, seed farmers must stock their fields with hives of pollinating bees to produce a seed crop. Pet.App.150a, 313a. As with other crops, however, alfalfa seed farmers use traditional stewardship measures, including isolation distances, to maintain varietal purity. *See* Pet.App.216a-17a, 212a-13a. According to the Association of Official Seed Certifying Agencies ("AOSCA"), isolation distances of 165, 450, and 900 feet between alfalfa seed fields are sufficient to ensure 99%, 99.75%, and 99.90% varietal purity, respectively. Pet.App.163a.

2. Roundup Ready Alfalfa

This case involves a variety of alfalfa created with the aid of modern biotechnology to address persistent problems caused by weeds in alfalfa fields. Weeds inhibit the growth of young alfalfa, Pet.App.126a-27a, and substantially reduce the nutritional (and thus economic) value of the mature crop, *id.*; Pet.App.133a-34a.

Herbicides can be used to combat the growth of weeds in alfalfa fields. The herbicides typically used are quite toxic, and federally mandated directions for their use require such measures as 24 hours' notice, on-site inspections to prevent "water contamination or drift into residential areas," and the use of "special

equipment (respirators, protective clothing and the like)." Pet.App.122a; *accord* JA-601-02 Many farmers would prefer to use Roundup agricultural herbicides, which control nearly every weed species in alfalfa crops, "dissipate[] rapidly in the soil" without residue, can be bought at any local hardware store, and can be used without any specialized safety equipment. Pet.App.122a. The Environmental Protection Agency ("EPA") has found the active ingredient in Roundup—glyphosate—to be one of the most environmentally responsible herbicides available commercially.[4] But applying Roundup to kill the weeds in conventional alfalfa fields would also destroy the alfalfa. Pet.App.305a-06a.

RRA was created to solve that problem. It is identical to conventional varieties in all respects but one—the insertion of a gene for glyphosate resistance that is found naturally in soil bacteria. Pet.App.43a, 127a; JA-172. Applying Roundup to RRA fields therefore kills the weeds without affecting the crop. Pet.App.127a, 133a-34a. This breakthrough permits farmers planting RRA to use a less toxic herbicide, less frequently, and at a lower cost. *See, e.g.*, JA-588-89, JA-596; Pet.App.122a. As one RRA farmer explained: "We normally apply four separate herbicides, plus cultivate three times, and still end up with a dirtier field than when we are able to just spray a low dose of RoundUp twice." JA-593. It is undisputed, moreover, that RRA is safe for human consumption and animal feed. Pet.App.43a, 286a.

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[4] Pet.App.195a-205a ("Glyphosate ... has favorable human health, ecological, and environmental fate profiles ...."); *accord* 67 Fed. Reg. 60,934, 60,935 (Sept. 27, 2002) (Glyphosate is "toxic to all green plants and essentially nontoxic to other living organisms.").

When the district court enjoined any further planting of RRA, approximately 220,000 acres of RRA had been planted in the United States, accounting for approximately 1% of total alfalfa acreage. Pet.App.64a, 330a.

3. Regulatory Approval of RRA

Since 1986, genetically engineered crops have been regulated under a "Coordinated Framework" by three different federal agencies: the Food and Drug Administration ("FDA"), EPA, and USDA. 51 Fed. Reg. 23,302, 23,302-09 (June 26, 1986). FDA is responsible for reviewing the safety of food and feed for humans and animals. *Id.*; 21 U.S.C. §§301 *et seq.* EPA examines potential health and environmental impacts of associated pesticide use under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§136 *et seq.* And USDA—through its Animal and Plant Health Inspection Service ("APHIS")—examines whether the crop presents a "plant pest" risk under the Plant Protection Act ("PPA"), 7 U.S.C. §§7701 *et seq.*; 7 C.F.R. §340.6(d)(3). RRA satisfactorily completed the review by all three federal agencies under this regulatory framework. FDA's conclusion that RRA is safe for humans and livestock is unchallenged, Pet.App.43a, and the district court dismissed respondents' action against EPA, JA-20 (docket entry 27). This case therefore concerns only APHIS's determination that RRA is not a plant pest.

Under USDA regulations, genetically engineered plants are presumed to be "plant pests"—and therefore "regulated articles" under the PPA—until APHIS determines otherwise. 7 C.F.R. §340.0(a)(2) n.1. After eight years of field testing, and following notice and public comment, APHIS concluded that RRA did not exhibit any "plant pest" characteristics and granted the

petition of Monsanto Company ("Monsanto") and Forage Genetics, Inc. ("FGI") (the owner and licensee of the relevant intellectual property, respectively) to provide RRA "Nonregulated Status." JA-151-231. That action—commonly referred to as "deregulation"—allowed RRA to be planted and sold commercially. Most alfalfa farmers and academic professionals supported the deregulation of RRA. JA-153. RRA was the 67th petition APHIS has granted since 1995 to deregulate a genetically engineered crop, and the 11th petition granted specifically for a glyphosate-resistant crop; other approved glyphosate-resistant crops include soy (1994), cotton (1995), corn (1997), canola (1999) and sugarbeets (2004).[5]

APHIS conducted its decision-making process subject to NEPA. NEPA is a procedural statute that does not mandate "particular results," *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350, 353 (1989), but rather requires federal agencies to prepare an environmental impact statement ("EIS") for every "major Federal action[] significantly affecting the quality of the human environment." 42 U.S.C. §4332(2)(C). An agency is not required by NEPA to prepare a full EIS if it determines, based on an environmental assessment ("EA"), that the proposed action will not have a significant impact on the environment. 40 C.F.R. §§1508.9(a), 1508.13; *see also DOT v. Public Citizen*, 541 U.S. 752, 757 (2004). In 2005, after receiving and reviewing some 663 comments, APHIS issued an EA and Finding of No Significant Impact ("FONSI") for RRA. JA-151-231.

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[5] *See* APHIS, EPA, *Petitions of Non-Regulated Status Granted or Pending by APHIS as of February 2, 2010*, http://www.aphis.usda.gov/brs/not_reg.html.

The FONSI obviated the need for APHIS to conduct an EIS. Pet.App.6a-7a.

PROCEEDINGS BELOW

Eight months after APHIS issued its EA and FONSI, respondents—a coalition of environmental organizations and individuals led by the Center for Food Safety—brought this action challenging APHIS's decision to deregulate the planting and sale of RRA. Among other things, respondents claimed that APHIS's action violated NEPA on the ground that a full-blown EIS was required. Pet.App.7a-8a. The district court granted summary judgment for respondents on their NEPA claim and entered a preliminary and then permanent nationwide injunction against the planting of any RRA until an EIS is completed. The Ninth Circuit affirmed.

1. District Court Proceedings

a. NEPA merits determination. In February 2007, the district court granted respondents' motion for summary judgment on their NEPA-based claim, and that decision is not challenged here. The court believed that the NEPA issue presented a "close question of first impression," but concluded that the possibility of cross-pollination from RRA to conventional and organic alfalfa would be a significant harmful impact on the human environment, and on that basis it ordered APHIS to prepare a full EIS. Pet.App.27a, 35a-45a, 51a-52a. In so holding, the district court emphasized that APHIS had deregulated RRA without imposing any mandatory isolation distances for RRA seed crops or other stewardship measures to prevent cross-pollination, and that RRA planting could occur "without any geographic restrictions." Pet.App.35a-45a, 52a.

b. APHIS's proposed tailoring measures. After the district court's ruling—and a full 21 months after APHIS's deregulation order—respondents for the first time moved for injunctive relief, insisting that the court prohibit all further planting and sales of RRA nationwide. In response, APHIS proposed a more tailored form of injunctive relief designed to eliminate any non-trivial likelihood of cross-pollination during the agency's preparation of its EIS. APHIS's proposal would have imposed precisely the sorts of traditional stewardship measures the district court had suggested. Among other things, it would have required:

(1) Specific isolation distances between RRA and non-RRA alfalfa seed production fields:

- 1500 feet for alfalfa crops pollinated by leafcutter bees, and
- 3 miles for crops pollinated by honey bees. Pet.App.161a-63a;

(2) Specific harvesting procedures for RRA hay alfalfa fields, including a requirement that the hay be harvested prior to bloom or 10% bloom if it is within 165 or 500 feet, respectively, of other alfalfa seed fields, Pet.App.163a-64a;

(3) Cleaning of planting and harvesting equipment after contact with RRA prior to its use on non-RRA, Pet.App.164a-65a;

(4) Identification and handling requirements for RRA seed before and after harvest, Pet.App.165a-66a; and

(5) Contracts between RRA growers and Monsanto and/or FGI that would require compliance with the four preceding conditions and other stewardship measures for the entire life of the RRA stand, Pet.App.166a.

APHIS explained that its proposal was based on its "many years of experience" regulating RRA, including 297 field trials over an 8-year period, as well as its experience with Roundup Ready corn, cotton, soybean, canola and sugarbeet crops. Pet.App.139a-40a. The 1500-foot to 3-mile isolation distances that APHIS proposed were significantly greater than the 900-foot isolation distance that RRA seed farmers had previously observed as a matter of contract, Pet.App.226a-27a, and that is judged sufficient by AOSCA for conventional seed farmers to achieve the 99.9% varietal purity necessary for "foundation seed," Pet.App.163a.

c. Evidence concerning the efficacy of APHIS's proposed measures. APHIS and petitioners—who intervened in support of the government at the remedial stage of the proceedings, Pet.App.8a—proffered substantial written evidence in support of APHIS's proposed tailored injunction.

The record showed that, if alfalfa is not harvested, the plants' stems will develop flower buds 25-30 days after they break ground and reach mid-bloom about 15-20 days after that. JA-625; Pet.App.347a. The flowers produce pollen that can be carried by bees. Pet.App.129a-30a. If a bee successfully pollinates another alfalfa flower, an ovule (immature seed) is formed that can develop into a mature seed over the course of more than a month. Pet.App.347a; *accord* Pet.App.281a. Harvesting during this period will destroy any developing seeds. Pet.App.130a, 231a, 282a, 409a-10a. If a mature seed does form and is permitted to germinate, it may develop into a new alfalfa plant. Pet.App.130a, 232a; JA-157, 457. However, if the seed falls and germinates near the existing crop—which it usually will, because alfalfa

seeds are too heavy to be carried far by the wind, Pet.App.232a—germination will likely be suppressed by a natural phenomena called autotoxicity whereby existing alfalfa plants prevent competition from new alfalfa plants by releasing natural toxins, Pet.App.130a, 232a, 279a.

Cross-pollination is not possible without pollen. And the evidence showed that alfalfa hay farmers have strong financial incentives to harvest their crops before they begin to bloom—much less produce any pollen—because flowering substantially decreases the nutritional (and hence financial) value of the crop. Pet.App.128a-29a; *accord* Pet.App.359a (protein content of alfalfa "highest just prior to flowering"). Failing to mow the hay even five to seven days after optimal harvesting time can result in a 30% loss of a crop's value. JA-625. For this reason, farmers will generally harvest alfalfa early, rather than risk significant blooming. Pet.App.128a. The diminution in value—and thus the incentive to harvest early—is even greater for organic hay. Pet.App.147a.

Dr. Neil Hoffman, Director of the Risk Analysis Division for the USDA Biotechnology Regulatory Services Division, explained that, because alfalfa grown for hay is harvested so early in its life cycle, with APHIS's proposed isolation distances and other stewardship measures in place, "no measurable GE contamination should occur" in organic or conventional hay crops from cross-pollination with RRA hay crops. Pet.App.147a-48a. Dr. Daniel H. Putnam, a world-renowned expert on alfalfa, stated that the possibility of cross-pollination from an RRA hay field to an adjacent non-RRA hay field would be approximately 2.5 in one million (0.00025%). Pet.App.280a-81a; *accord* Pet.App.160a (such cross-pollination will be

"negligible"), 229a-35a ("virtually non-existent"), 378-80a ("near zero probability").[6]

For many of the same reasons, the evidence showed that cross-pollination from RRA hay fields to conventional or organic *seed* fields is also highly unlikely. Dr. Larry Teuber, another highly regarded expert on alfalfa, explained that such cross-pollination was "rarely detected (0.00 to 0.05%)" at distances of greater than 350 feet even if honey bees were used as pollinators, the hay field were at 20% bloom, and the seed crop were simultaneously at 100% bloom. JA-579-82, 484-90. And Dr. Hoffman similarly concluded that, with APHIS's measures in place, cross-pollination from RRA hay crops to non-RRA seed crops would range from "below 0.1%" to "essentially zero." Pet.App.164a; *accord* Pet.App.148a-50a, 161a-62a, 278a-79a.

Since field testing began in 1998, and in the twenty-one months RRA was deregulated before the district court's injunction, there was *no* evidence of *any* cross-pollination from the 200,000 acres of RRA hay fields to any other alfalfa crop—hay or seed. Pet.App.64a, 277a-78a, 408a-09a. And even respondents' own declarant admitted that hay crops do not present "any substantial risk of gene flow." Pet.App.359a.

The government's and petitioners' experts further explained that the possibility of cross-pollination from

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[6] In response to a question posed by the district court at the oral argument on the preliminary injunction, FGI President Mark McCaslin, stated that, because weather conditions can sometimes delay the harvest, it would be a "disaster" to require farmers to harvest before bloom in all cases. JA-552-54. McCaslin made clear, however, that even if rain delayed harvesting for multiple days until after first bloom, there would still be "nil opportunity for pollen flow from hay to hay." JA-552-54.

RRA seed fields to other alfalfa seed fields would also be "extremely low" or "de minimis" with APHIS's proposed measures in place. Pet.App.227a-29a, 234a-35a, Pet.App.256a-57a; JA-575-78. Under the proposed stewardship measures, Dr. Hoffman estimated that seed-to-seed transmission levels would be at or below 0.1% for seed fields stocked with leafcutter bees and less than 0.03% for seed fields stocked with honey bees, if it occurred at all. Pet.App.162a-63a, 178a; *accord* Pet.App.227a-29a.

The evidence showed that seed-to-hay cross-pollination is even less likely, because hay crops are generally harvested before any significant bloom, and weeks or months before any developing seed in a hay crop could mature. JA-574; Pet.App.231a-32a; *supra* at 11-13. Dr. Hoffman explained that no measurable gene contamination should occur in non-RRA hay crops, from either RRA hay or seed crops. Pet.App.148a. Indeed, there has never been a single reported incident of cross-pollination from RRA seed fields to the approximately 22 million acres of conventional and organic alfalfa hay crops grown domestically. Pet.App.408a-09a.

Respondents reacted to this scientific evidence mostly with second-hand anecdotal accounts of supposed cross-pollination. Petitioners objected to all of that evidence as inadmissible hearsay, JA-47, 59, 69, 70-71 (docket entries 117, 160, 184, 187), but the district court never ruled on their objections and never permitted petitioners to subject the statements to cross-examination, Pet.App.60a-79a. In any event, even if taken at face value none of the respondents' submissions suggested that cross-pollination would be likely with APHIS's proposed mitigation measures in place. *See infra* at 46-47.

d. Evidence concerning the balance of harms. Petitioners demonstrated that respondents' alternative to APHIS's tailored remedy—a nationwide blanket injunction against any further planting of RRA—would inflict substantial and completely unnecessary financial harm on approximately 3,000 RRA farmers located in 48 states. Pet.App.142a-47a. Dr. Nantell, an economist, estimated that farmers who have planted or would plant RRA would lose more than $200 million in just the first two years of such an injunction. Pet.App.267a-69a; JA-1026-54. In addition, seed companies, seed distributors, and dealers would lose another estimated $20 million, Pet.App.268a-69a, and Monsanto would suffer roughly $27 million in lost technology royalties. JA-584-85.

In contrast, there was no evidence that any respondents had ever experienced *any* cross-pollination from RRA crops to their conventional or organic crops. There was also no evidence that, because of RRA, any organic alfalfa farmers had ever been unable to sell their hay or seed crops as organic, lost certification as an organic grower, or lost any export sales. To the contrary, the record showed that organic alfalfa farmers were unlikely to lose any foreign sales. Lacking evidence of any actual or imminent commercial injury, and any non-hearsay evidence of cross-pollination, respondents submitted declarations of farmers who subjectively feared that cross-pollination could occur in the future and offered their unsupported beliefs that such cross-pollination was inevitable. *See, e.g.*, JA-666 ("While I have not been contaminated yet, I believe it is only a matter of time.").

e. Entry of injunctive relief. The district court nonetheless rejected APHIS's tailored approach, both

in its preliminary and permanent injunction decisions. In its preliminary injunction order, the court did not identify any likelihood of irreparable harm with or without APHIS's proposed stewardship measures in place, and indeed did not bother to analyze the traditional equitable factors for issuance of injunctive relief at all. Pet.App.54a-59a. Instead, following Ninth Circuit precedent, the court operated from the premise that, "[i]n the run of the mill NEPA case, the contemplated project ... is simply delayed until the NEPA violation is cured" and that, "absent unusual circumstances, an injunction is the appropriate remedy for a violation of NEPA's procedural requirements." Pet.App.55a (internal quotation marks and citations omitted). Accordingly, the court issued a nationwide injunction against "all future planting" or sales of RRA seed after March 30, 2007. Pet.App.56a-58a.[7]

The district court relied on the same basic understanding when assessing the appropriateness of permanent injunctive relief. The court refused petitioners' request for an evidentiary hearing to demonstrate the unlikelihood of cross-pollination with APHIS's stewardship measures in place, and refused to rule on petitioners' evidentiary objections to respondents' submissions. *See* JA-46-47, 59, 69 (docket entries 116, 117, 160, 184); Pet.App.67a-68a. Instead of holding an evidentiary hearing, the court held an "oral

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[7] The court permitted the growing, harvesting, and selling of RRA hay already planted before March 30, 2007, subject to certain of APHIS's (otherwise rejected) stewardship measures imposed to "minimize the risk of gene flow." Pet.App.75a-78a. Because alfalfa is a perennial crop that generally lasts three to five years, Pet.App.126a, harvesting of already-planted RRA is still ongoing, subject to those stewardship measures.

argument" on respondents' request for a permanent injunction. Pet.App.58a-59a.

At that argument, the court made plain its belief that it did not need to resolve the parties' dispute over the likelihood of irreparable harm:

> So I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it .... It just seems to me that ... I could be like a super environmental agency engaged in balancing all these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And number two, it isn't my job .... I should stop things in its place until the Government has discharged its duty given to it by the right of Congress of the United States.

Pet.App.417a.

The district court reaffirmed that position in its permanent injunction order. The court acknowledged that "intervenors have requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed." Pet.App.67a. But it denied that request, reiterating its refusal "to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." Pet.App.68a. The court also reiterated its understanding that injunctive relief should issue "[i]n the run of the mill NEPA case" and that "'more liberal standards for granting an injunction'" apply in NEPA cases. Pet.App.55a, 65a-66a (citations omitted).

The district court simply refused to consider tailoring its injunction based on the unrefuted efficacy

of the isolation distances and other stewardship measures proposed by APHIS or, for that matter, the possibility of mandating even greater isolation distances. Pet.App.68a-70a, Pet.App.192a ("I am not going to get into isolation distances."). It entered a blanket nationwide injunction against any further planting of RRA without ever finding that irreparable harm would be "likely" with the government's proposed mitigation measures in place. Pet.App.60a-79a.

To the extent the district court adverted to the traditional equitable factors for the issuance of injunctive relief, it did so only cursorily. Pet.App.71a-72a, 75a. Without making any effort to analyze the government's and petitioners' expert declarations about how remote the possibility of harm would be under APHIS's proposed stewardship measures, or allowing any cross examination of respondents' contrary declarants, the district court stated that "plaintiffs h[ad] *sufficiently* established irreparable injury." Pet.App.71a (emphasis added). At that time, the Ninth Circuit considered proof of "a 'possibility' of irreparable harm" sufficient to enter an injunction. *Winter*, 129 S. Ct. at 374-76; *accord Or. Natural Res. Council Fund v. Goodman*, 505 F.3d 884, 898 (9th Cir. 2007).

The district court grounded its conclusion that respondents established a "sufficient likelihood" of irreparable injury on (1) respondents' hearsay allegations that some "contamination has occurred" in certain seed crops under conditions "similar to" those proposed by APHIS, (2) the theoretical possibility that extreme weather conditions—such as months of continuous rain—might so delay a harvest as to permit hay-to-hay cross-pollination, and (3) skepticism that

APHIS would have sufficient resources to ensure compliance with its proposed stewardship measures. Pet.App.69a-71a.

In addition to enjoining APHIS from permitting any further planting of RRA nationwide, the district court went even further, and prohibited APHIS on remand from adopting any interim solution that would allow commercial planting before an EIS was completed. Pet.App.108a.

2. Ninth Circuit Proceedings

a. Original opinion. Like the district court's judgment, the Ninth Circuit's original opinion was issued before this Court's decision in *Winter*, when Ninth Circuit law counted a mere "possibility" of irreparable harm sufficient to support injunctive relief. 129 S. Ct. 374-76. Under that standard, the Ninth Circuit affirmed the district court's judgment in all respects. The court concluded that the district court had properly applied the traditional equitable factors before issuing an injunction, including likelihood of irreparable harm. Pet.App.90a-92a. Despite the absence of an evidentiary hearing, the Ninth Circuit reviewed the "factual findings" of the district court only for clear error, and found the district court's conclusion that irreparable harm was "sufficiently likely" not clearly erroneous. Pet.App.91a-92a.

Although the court acknowledged that "[t]he parties' experts disagreed over virtually every factual issue" relating to possible environmental harm, Pet.App.87a (quotation marks omitted), it also affirmed the denial of an evidentiary hearing. The court explained that petitioners "had [not] established any *material* issues of fact" necessitating an evidentiary hearing, because "the disputed matters [were] issues more properly addressed by the agency in the

preparation of an EIS" and there was no reason for the district court to "duplicate the [agency's] efforts." Pet.App.95a-96a. The court further observed that a NEPA-based injunction "has a more limited purpose and duration" and thus is "not a typical permanent injunction, which is of indefinite duration." *Id.*

Judge Smith dissented. He explained that the absence of an evidentiary hearing was a "critical failure ... [that] deprived the parties of important procedural rights," Pet.App.100a, and that the exception would apply broadly: "There aren't many environmental cases that don't fit into the majority's newly-created exemption." Pet.App.102a. "Based on [the] record," moreover, Judge Smith had "serious concerns about the scope of the injunction entered by the district court." Pet.App.101a-02a. He found no basis for the district court's "nationwide injunction on the planting of Roundup Ready alfalfa while APHIS completes an EIS," an injunction which had "severe economic consequences." *Id.*

b. Amended opinion. In response to petitioners' rehearing petition and supplemental filings, which highlighted this Court's intervening decision in *Winter*, the Ninth Circuit vacated its original opinion and issued an amended opinion on denial of rehearing. Pet.App.107a. That amended opinion suggested—for the first time—that the district court actually *did* hold an evidentiary hearing because it permitted Mark McCaslin, president of petitioner FGI, to address the court with unsworn statements from counsel's table at the oral argument on respondents' preliminary injunction motion. Pet.App.23a. But the amended opinion also adhered to the court of appeals' original statements that the "district court here correctly denied a hearing," and that "[w]hat the district court

did not do was to hold an additional evidentiary hearing to resolve the very disputes over the risk of environmental harm that APHIS would have to consider in the EIS." Pet.App.19a-20a.

The amended opinion did not discuss *Winter*'s holding that the traditional equitable standards, including a finding of likely irreparable harm, must all be satisfied to justify injunctive relief for a NEPA violation. Instead, the Ninth Circuit merely added a cite to *Winter* as support for a *preexisting* sentence approving the district court's conclusion that irreparable harm was "sufficiently likely" to warrant an injunction. *Compare* Pet.App.13a *with* Pet.App.91a.

3. Ongoing EIS Proceedings

APHIS released a draft EIS on December 18, 2009, recommending that RRA again be deregulated. 74 Fed. Reg. 67,206 (Dec. 18, 2009). Comments on that draft EIS were initially due on February 16, 2010, *id.*, but the comment period has been extended to March 3, 2010.[8] APHIS has not set a schedule for releasing a final EIS. Meantime, the district court's blanket injunction remains in effect.

SUMMARY OF ARGUMENT

I. This Court has repeatedly emphasized that injunctive relief is an "extraordinary remedy" that is "never awarded as of right" and instead is only available after a careful consideration of the traditional equitable factors. *Winter v. NRDC*, 129 S. Ct. 365, 374-

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[8] APHIS, USDA, News Release, *USDA Extends Comment Period on Draft Environmental Impact Statement for Genetically Engineered Alfalfa*, http://www.aphis.usda.gov/newsroom/content/2010/02/alfalext.shtml.

77 (2008). In upholding the injunction at issue, the Ninth Circuit deviated from that critical restraint on the exercise of judicial authority in several fundamental respects.

First, the injunction is predicated on the misguided view that injunctive relief is invariably warranted in the case of a NEPA violation pending the outcome of an EIS. This Court has emphatically rejected the notion that the procedural violation of a statute requiring environmental review justifies an injunction against the underlying conduct until that assessment is completed. *See, e.g., Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531 (1987). In entering the injunction at issue, however, the district court declined to engage in any serious inquiry into the likelihood of irreparable harm on the ground that the agency was going to "conduct[] ... the very same scientific inquiry" in conducting an EIS. Pet.App.68a. And the Ninth Circuit similarly deemed the entire issue of likelihood of irreparable harm to be *immaterial* on the ground that the EIS would serve as a substitute for the analysis of alleged environmental harm that the district court refused to conduct. In other words, the courts below effectively resurrected the very type of presumption of irreparable harm in environmental cases that this Court has condemned. *Amoco*, 480 U.S. at 544-45.

Second, the court erred in failing to insist on the requisite showing of "irreparable injury" that "is *likely* in the absence of an injunction." *Winter*, 129 S. Ct. at 375. *Winter* establishes that this requirement applies with full force to NEPA cases and that the "*possibility* of irreparable harm" is insufficient to support the entry of injunctive relief. *Id.* at 375-76 (emphasis added). As in *Winter*, however, the record here conclusively

precludes a finding of the requisite *likelihood* of irreparable harm when viewed in light of APHIS's tailored injunction (to which petitioners do not object).

In entering the injunction, the district court relied on the "potential," Pet.App.72a, of two harms that it believed could flow from the use of RRA—(1) the total extinction of conventional alfalfa, and (2) cross-pollination with conventional alfalfa in individual farmers' fields. By definition, a "potential" harm is not sufficient under *Winter*. But in any event the first of these alleged harms is simply fanciful, and the second is neither likely nor cognizable as irreparable harm to the environmental interests that NEPA was enacted to protect. The Ninth Circuit's holding that "genetic contamination was sufficiently likely to occur so as to warrant broad injunctive relief," Pet.App.13a, is belied by the record evidence, and ultimately is a product of the court's mistaken legal view that the agency's impending EIS process is an appropriate *substitute* for the Judiciary's own responsibility to ensure that the requirements for injunctive relief—including the likelihood of irreparable harm—are met before an injunction is entered.

Third, the injunction is grossly overbroad because the district court dismissed out of hand the tailored injunction proposed by the expert federal agency charged with overseeing genetically engineered crops. This Court has made clear that an injunction must be "no more burdensome to the defendant than necessary." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). The isolation distances and stewardship measures proposed by APHIS were more than sufficient to prevent any conceivable irreparable harm through cross-pollination. Both the district court and Ninth Circuit nevertheless refused to "get into the

isolation distances" and the like, Pet.App.192a, because they simply assumed that a blanket injunction was required pending the agency's completion of an EIS and, worse, assumed that the government could not competently enforce such measures anyway. The Ninth Circuit's refusal to treat the injunction as anything other than an all-or-nothing proposition is flatly inconsistent with this Court's teachings and alone necessitates reversal of the decision below.

II. Even setting to one side the Ninth Circuit's flawed conception of the equitable factors governing the entry of injunctive relief, the judgment below must still be reversed because petitioners were improperly denied an evidentiary hearing on the likelihood of irreparable harm.

The right to an evidentiary hearing with live witnesses and the opportunity for cross-examination is a fundamental and time-honored component of our judicial system. The Federal Rules of Civil Procedure and due process require an evidentiary hearing upon request whenever there are genuine disputes of material fact. At a bare minimum, there was at least a material issue of fact as to whether any irreparable harm was likely. In reaching its contrary decision, the Ninth Circuit reasoned that disputes as to the likelihood of irreparable harm in NEPA cases are categorically *immaterial* and that evidentiary hearings are not warranted with respect to NEPA-based injunctions because such injunctions are uniquely temporary. Both rationales ultimately stem from the Ninth Circuit's misguided view that requiring a plaintiff to show a likelihood of irreparable harm is somehow unduly "duplicat[ive]" of the agency's efforts—and therefore unnecessary—in NEPA cases. Pet.App.19a. And neither rationale finds any support

in the text of NEPA, the Federal Rules of Civil Procedure, or, for that matter, any other authority.

ARGUMENT

I. EQUITABLE PRINCIPLES REQUIRE THE ENTRY OF USDA'S NARROWLY TAILORED INJUNCTION

An injunction is an "extraordinary and drastic remedy" that is "never awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008) (quotation marks omitted). As this Court reiterated last Term, a plaintiff seeking an injunction must satisfy the traditional equitable test, demonstrating that (1) "he is likely to suffer irreparable harm," (2) "remedies available at law, such as monetary damages, are inadequate to compensate for that injury," (3) "the balance of equities tips in his favor," and (4) "an injunction is in the public interest." *Winter*, 129 S. Ct. at 374; *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006). That required showing by plaintiffs is *in addition to* the threshold demonstration that the defendant's conduct is unlawful, unless the statute provides otherwise "in so many words, or by a necessary and inescapable inference." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982). The injunction entered by the district court and upheld by the Ninth Circuit in this case departs from those settled principles in several fundamental respects.[9]

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[9] To be clear, petitioners have not challenged the tailored injunction proposed by APHIS. Pet.App.184a-87a. Their objection is to the *blanket* injunction entered by the district court against all planting of RRA. Accordingly, if this Court agrees with petitioners that the blanket injunction is unfounded, it may remand with instructions to enter the tailored injunction. *Cf. Winter*, 129 S. Ct. at 376, 382 (Navy challenged only two aspects of

A. The Injunction Is Predicated On The Mistaken View That NEPA Cases Warrant A Special Rule For Injunctive Relief

1. This Court has repeatedly rejected the proposition that the procedural violation of a statute—like NEPA—requiring environmental review as a precondition to government action justifies the entry of an injunction against the underlying conduct until the assessment is completed or warrants dispensing with the requirement of showing a likelihood of irreparable harm if an injunction is not entered.

In *Weinberger*, for example, this Court reversed the First Circuit's holding that federal courts had an "'absolute statutory obligation'" to issue an injunction after finding a procedural violation of the Clean Water Act ("CWA"). 456 U.S. at 311 (citation omitted). The Court observed "that a major departure from the long tradition of equity practice should not be lightly implied." *Id.* at 320. And the Court found no evidence in the CWA that "Congress intended to deny courts their traditional equitable discretion" in determining whether an injunction was warranted, *id.* at 319, including proof of a likelihood of actual irreparable harm to the underlying environmental interests. *See id.* at 312 ("[T]he basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies ....") (citing numerous cases).

Five years later, in *Amoco Production Co.*, this Court expressly rejected the proposition that a procedural violation of an environmental statute (there,

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preliminary injunction at issue and Court vacated injunction only "to the extent it has been challenged by the Navy").

the Alaska National Interest Lands Conservation Act) created a presumption of irreparable harm to the environment. 480 U.S. at 542-45. The Court explained that such a "presumption is contrary to traditional equitable principles." *Id.* at 545. And after reviewing the evidentiary record in the case the Court concluded that—notwithstanding the government's failure to perform the requisite environmental evaluation—irreparable harm was actually "not at all probable," and on that basis vacated the injunction. *Id.* at 545-47.

Last Term in *Winter*, this Court removed any doubt that these principles—and the traditional equitable factors—apply equally to injunctions sought to remedy NEPA violations. 129 S. Ct. at 374. The procedural violation in *Winter* was the same as that here: the agency had erroneously concluded that an EIS was not required in approving the action at issue. The Court criticized the Ninth Circuit's then-prevailing "'possibility' [of harm]" standard as "too lenient," *id.* at 375, emphasized that the Court's "frequently reiterated standard requires plaintiffs seeking [injunctive] relief to demonstrate that irreparable injury is *likely* in the absence of an injunction," and held unequivocally that a district court may not enter an injunction for a NEPA violation broader than necessary to prevent a "likelihood" of irreparable harm pending the government's preparation of an EIS, *id.* at 374-76.

2. Contrary to the holdings of *Weinberger*, *Amoco*, and *Winter*, the injunction upheld in this case is predicated on the notion that a procedural violation of NEPA itself warrants a blanket injunction against the underlying conduct, and the lower courts thus dispensed with any serious examination of whether substantive environmental harm would occur in the absence of a blanket injunction. The district court was

forthright in that view. The court candidly observed that it "isn't my job" to assess the "environmental impact" of allowing the challenged action to proceed, explaining that "I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it." Pet.App.417a. And on that basis, the district court refused to "conduct ... the very same scientific inquiry [it had] ordered APHIS to do." Pet.App.68a, 417a; *accord supra* at 17-18. Instead, the district court concluded that in the "'run of the mill NEPA case,'" an injunction is appropriate "'until the NEPA violation is cured.'" Pet.App.55a (quoting *Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 833 (9th Cir. 2002)).

Moreover, because it erroneously believed that, as a matter of principle, conduct authorized without full NEPA compliance must be enjoined pending the completion of an EIS, the district court "reject[ed]" out of hand the notion that interim measures allowing continued planting of RRA could ever be appropriate as a NEPA remedy, regardless of the likely effectiveness of accompanying stewardship requirements. In the court's words, APHIS should not be permitted to "skip the EIS process and decide without any public comment that deregulation with certain conditions [*i.e.*, the proposed interim measures] is appropriate." Pet.App.69a.

For its part, the Ninth Circuit articulated the showings that must be made under the traditional equitable test, and acknowledged that the test applies in environmental cases. Pet.App.11a-12a. But when the rubber met the road, the court agreed with the district court that there was no need for the Judiciary to sort out whether irreparable harm could be prevented by APHIS's proposed stewardship

measures, since APHIS would be addressing the potential harms from RRA in any event when preparing the EIS, and that it was appropriate simply to ban all new planting nationwide for the time being. Pet.App.16a, 18a-20a. As a result, while it recites the traditional equitable factors, the Ninth Circuit's decision effectively sanctions the same presumption of irreparable harm and injunctive relief for NEPA cases adopted by the district court.

The Ninth Circuit couched its rule in terms of whether petitioners had identified a "material" dispute over the risk of environmental harm. As the court put it, the parties' disagreement over the likelihood of irreparable harm under APHIS's more tailored proposal was not "material" because "the disputed matters [were] issues more properly addressed by the agency in the preparation of an EIS" and there was no reason for the district court to "'duplicate the [agency's] efforts'" and "'divert [its] resources.'" Pet.App.17a-19a. (quoting *Idaho Watersheds*, 307 F.3d at 831). The Ninth Circuit thus viewed the agency's impending EIS process as a *substitute* for judicial weighing of the traditional equitable standards for injunctive relief, observing that the district court need only "'allow for a[n] [EIS] process to take place which will determine permanent measures.'" Pet.App.18a-19a (citation omitted)

To be sure, the Ninth Circuit, Pet.App.13a, did disclaim the presumption of irreparable environmental harm that this Court squarely rejected in *Amoco*, 480 U.S. at 544-45. But allowing district courts to issue injunctions in NEPA cases without adjudicating the likelihood of irreparable harm—in the name of avoiding any "duplicat[ion]" of the agency's efforts in completing the EIS, Pet.App.19a—amounts to the same thing.

And a court may not circumvent this Court's precedents by engaging in the two-step of simply referencing the applicable rule and then disregarding it.[10]

Indeed, *Weinberger*, *Amoco*, and *Winter* all involved the same potential "duplication" of efforts on which the Ninth Circuit relied here. The agencies in each of those cases were ordered to conduct additional environmental analyses just as APHIS was in this case. *See Winter*, 129 S. Ct. at 376, 381 & n.5 (Navy conducting ongoing EIS); *Amoco*, 480 U.S. at 538-39 (noting that the "Secretary prepared a postsale [environmental] evaluation" "[i]n compliance with the Court of Appeals' decision"); *Weinberger*, 456 U.S. at 315 n.9 (Navy application for CWA permit under consideration by EPA). But, in each instance, this Court nonetheless required a judicial determination of the traditional equitable factors before any injunction could issue. The same should hold true here.

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[10] The Ninth Circuit has similarly observed that "injunctive relief is the appropriate remedy for a violation of an environmental statute absent rare or unusual circumstances." *Owner-Operator Indep. Drivers Ass'n v. Swift Transp. Co.*, 367 F.3d 1108, 1114, 1423 (9th Cir. 2004) (quoting *People of Gambell v. Hodel*, 774 F.2d 1414, 1423 (9th Cir. 1985), *rev'd*, 480 U.S. 531 (1986); *see* Pet.App.12a (referencing "unusual circumstances" test). That standard is not only directly at odds with this Court's repudiation of a presumption in favor of injunctive relief in environmental cases in *Amoco*, 480 U.S. at 544-45, but it is nearly identical to the standard for injunctive relief that this Court invalidated in *eBay*, 547 U.S. 388. *See id.* at 392-94 (unanimously rejecting the Federal Circuit's standard that an injunction should issue except in an "'unusual' case," "under 'exceptional circumstances,'" or "'in rare instances'" as contrary to traditional equitable principles) (citation omitted).

3. Because the finding of a NEPA violation almost always leads to a court order requiring the defendant agency to perform additional environmental analysis, the Ninth Circuit's holding in this case creates a special NEPA exception to the rule that an injunction will not issue except as necessary to prevent a likelihood of irreparable harm. And that exception would by its logic extend equally to other statutes requiring environmental analyses as a precondition to agency action. As Judge Smith rightly observed in dissent, "[t]here aren't many environmental cases that don't fit into the majority's newly-created exemption." Pet.App.102a. This exception conflicts squarely with this Court's holdings in *Weinberger*, *Amoco*, and *Winter* that the traditional equitable standards for an injunction apply with full force in this statutory context. *Winter*, 129 S. Ct. at 374-76; *Amoco*, 480 U.S. at 542-45; *Weinberger*, 456 U.S. at 310-13.

The Ninth Circuit rule also is at odds with this Court's "well settled" holding that "NEPA itself does not mandate particular results." *Robertson*, 490 U.S. at 350 (collecting cases); *Winter*, 129 S. Ct. at 376 ("NEPA imposes only procedural requirements ...."). Congress did not even provide a cause of action for NEPA claims, let alone carve out a special exemption from the traditional factors governing the entry of the "extraordinary and drastic remedy"[11] of an injunction in NEPA cases. *See, e.g.*, *Tulare County v. Bush*, 306 F.3d 1138, 1143 (D.C. Cir. 2002), *cert. denied*, 540 U.S. 813 (2003); *see also Weinberger*, 456 U.S. at 313 (holding that the traditional prerequisites for injunctive relief apply unless a statute "in so many words, or by a necessary and inescapable inference"

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[11] *Munaf*, 128 S. Ct. at 2219.

provides otherwise). Nor is an exception from the traditional equitable standards—including likelihood of irreparable harm—remotely necessary to address NEPA violations. As this Court explained in *Winter*, courts have "many remedial tools at [their] disposal, including declaratory relief or an injunction tailored to the preparation of an EIS rather than the [complete ban of the challenged government activity] in the interim." 129 S. Ct. at 381.

The Ninth Circuit's NEPA exception is also fundamentally misguided as a matter of jurisprudence. This exception is seemingly based on the belief that proof of a likelihood of irreparable harm is immaterial because, albeit "permanent," an injunction pending release of an EIS is as a practical matter "temporary." But that rationale runs headlong into this Court's precedents recognizing that even a preliminary injunction—which by definition is a temporary measure—is an "extraordinary remedy" that requires (among other things) proof of a likelihood of irreparable harm. *See, e.g., id.* at 374-76; *Munaf*, 128 S. Ct. at 2219; *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam). Indeed, as this Court has observed, "[t]he standard for a preliminary injunction is essentially the same as for a permanent injunction." *Amoco*, 480 U.S. at 546 n.12.

Finally, to the extent the Ninth Circuit views its exception in NEPA cases to the requirement of showing a likelihood of irreparable harm as an appropriate reluctance to prejudge issues that would be addressed by APHIS in the course of its EIS, it is a uniquely non-deferential form of judicial abstention. Indeed, as Judge Smith observed, "[b]y picking and choosing when to afford deference, the court's deference is tantamount to no deference at all."

Pet.App.23a. Instead of deferring to the agency's expert view of the protections necessary to avoid meaningful cross-pollination from RRA during its preparation of an EIS, the court of appeals affirmed a nationwide injunction that the agency considers to be—and that is—fatally overbroad and entirely unnecessary. And ultimately it is the *court's* duty—not an agency's—to determine whether the traditional equitable factors governing injunctive relief are met.

B. The Injunction Is Not Supported By The Requisite Showing Of A Likelihood Of Irreparable Harm

Regardless of whether the Ninth Circuit has effectively resurrected the same kind of presumption invalidated in *Amoco*, the courts below erred in failing to insist on the requisite showing of "irreparable injury" that "is *likely* in the absence of an injunction." *Winter*, 129 S. Ct. at 375. *Winter* removes any doubt that this requirement applies with full force to NEPA cases and explains that "[i]ssuing [an] injunction based only on a *possibility* of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 375-76 (emphasis added). Yet, to the extent that the district court even addressed the issue of irreparable harm, it based its injunction on the *possibility* of two harms it believed could flow from the use of RRA: the (1) total extinction of conventional alfalfa, and (2) cross-pollination with conventional alfalfa in individual farmers' fields.[12] The first of these

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[12] *Compare* Pet.App.92a (referencing "potential[]" of RRA to "eliminate the availability of non-genetically engineered alfalfa")

possible harms is inconceivable, and the second is neither likely nor cognizable as irreparable harm to the environment—the protection of which is the sole purpose of NEPA.

1. There is no likelihood that RRA will eliminate conventional alfalfa.

The district court's suggestion that continued planting of RRA could eliminate the availability of conventional alfalfa is bad science fiction with no support in the record. The record makes clear that the likelihood of RRA displacing all non-RRA alfalfa—particularly in the time period while an EIS is being prepared—is *zero*.

To begin with, RRA is not "contagious." Cross-pollination from RRA does not alter the genetic composition of the recipient alfalfa plants. Only the *seed* produced from that rare cross-pollination would have the RRA gene. Pet.App.147a, 386a-87a, 409a-10a. If that seed then matured, germinated, and developed into a new alfalfa plant—which is highly unlikely in the ordinary course—the plant would have the selective advantage of glyphosate resistance. Pet.App.398a. But as most alfalfa farmers do not use glyphosate (Pet.App.122a, 240a) and no organic farmers do so (Pet.App.263a-64a, 401a), that selective advantage does not give RRA any evolutionary edge in most farmers' fields. The notion that cross-pollination from RRA threatens to eliminate all conventional varieties of

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and Pet.App.75a (analyzing "potential of eliminating the availability of a non-genetically engineered crop"), *with* Pet.App.13a (relying on individual instances of "genetic contamination" that "had already occurred") *and* Pet.App.71a (reasoning "contamination of organic and conventional alfalfa crops ... is irreparable environmental harm").

alfalfa ignores those basic principles of biology. Pet.App.387a-88a, 397a-98a, 413a.

The extinction rationale is particularly unsound given that RRA was grown without any governmental restrictions for 21 months prior to the district court's injunction with no sign that any disappearance of conventional alfalfa was in the offing. RRA currently constitutes but 1% of total alfalfa planted in the United States, and it was projected that RRA's market share would have grown only to 2-3% during the pendency of the EIS process. JA-621.

2. Individual instances of cross-pollination at particular farms could not constitute irreparable environmental harm.

As discussed below, with APHIS's proposed stewardship measures in place, the probabilities of cross-pollination from RRA hay or seed fields to other farmers' conventional or organic crops are exceedingly remote. *Infra* at 41-47. But even aside from those exceptionally low probabilities, the idea that low-level cross-pollination affecting individual farms qualifies as irreparable environmental harm is itself fundamentally flawed.

The remote possibility of sporadic cross-pollination of conventional crops with neighboring RRA, however unwanted by the conventional or organic farmer, is not a cognizable environmental harm under NEPA and therefore not an appropriate cause for an injunction to remedy a NEPA violation. It is axiomatic that an injunction to remedy a statutory violation may not extend beyond the interests of the underlying

statute.[13] NEPA was enacted to "protect[] and promot[e] *environmental* quality." *Robertson*, 490 U.S. at 348 (emphasis added). Moreover, injunctions are necessarily limited to "remedy[ing] the specific harm shown"—here a failure to adequately consider potential *environmental* impacts. *Neb. HHS v. HHS*, 435 F.3d 326, 330 (D.C. Cir. 2006) (quotations omitted); *accord Kentuckians for the Commonwealth, Inc. v. Rivenburgh*, 317 F.3d 425, 436 (4th Cir. 2003) (holding that injunctions may not "go beyond the extent of the established violation") (quotations omitted)). The possibility of low levels of cross-pollination in a small number of individual farms is simply not harm to the "human environment" in any meaningful sense.

In order to cause the sort of irreparable environmental injury that could justify a nationwide injunction, a plaintiff must demonstrate "irretrievabl[e] damage [to] the species." *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975) (refusing to "equate the death of a small percentage of a reasonably abundant game species with *irreparable* injury"); *accord Water Keeper Alliance v. U.S. DoD*, 271 F.3d 21, 34 (1st Cir. 2001) (holding death of a "'single

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[13] *See, e.g., Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 292 (1960) (injunctions provide "relief in light of the statutory purposes"); *Amoco*, 480 U.S. at 544 (equitable relief not justified by harm to the "statutory procedure" but rather only by likely harm to the "underlying substantive policy the process was designed to effect"); *Weinberger*, 456 U.S. at 314 (restricting injunctive relief to the "purpose of the [Clean Water Act]", *i.e.*, "[t]he integrity of the Nation's waters"); *Hecht Co. v. Bowles*, 321 U.S. 321, 331 (1944) (holding equitable discretion "must be exercised in light of the large objectives of the Act"), *United States v. Mass. Water Res. Auth.*, 256 F.3d 36, 48 (1st Cir. 2001) (injunctions "must be cabined by the purposes for which the statute was created").

member of an endangered species'" was "insufficient" absent showing of how "probable deaths ... may impact the species" (citation omitted)). That makes perfect sense, because absent species-level harm there is no meaningful change in the environment, let alone irreparable environmental injury. *Id.* And the *sole* alleged "environmental" harm advanced by respondents here is the possibility of a diffuse change in the composition of alfalfa plants based on the relative frequency of a single gene, which is irrelevant (and confers no selective advantage) in the natural environment, where glyphosate is not applied. Pet.App.122a, 240a, 398a.

Whether an individual farmer plants an orange orchard rather than a corn field is a much greater change in the environment than whether a particular farmer has 99.9% instead of 99.99% varietal purity in his crops. But neither makes any meaningful difference to the environment as a whole. This Court has cautioned against "seiz[ing] the word 'environmental' out of its context and giv[ing] it the broadest possible definition," which would result in NEPA "embrac[ing] virtually any consequence of a governmental action that someone thought 'adverse.'" *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 772 (1983). This is precisely what respondents have done here—attempting to dress up what amounts to a disagreement about agricultural policy into an alleged environmental impact. *But see id.* at 777 ("The political process, and not NEPA, provides the appropriate forum in which to air policy disagreements.").[14]

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[14] Respondents oppose the government's approval of *any* genetically engineered crops as a matter of policy. The express

The principal harm alleged by respondents is, actually, purely economic—*i.e.*, the diminished value of a crop "contaminated" with RRA in the market for organic alfalfa. That is not an environmental harm by any stretch. And remedying such an economic harm is simply not one of NEPA's purposes. *See, e.g., Rosebud Sioux Tribe v. McDivitt*, 286 F.3d 1031, 1038 (8th Cir. 2002) ("'The purpose of NEPA is to protect the environment, not the economic interests of those adversely affected by agency decisions.'" (citation omitted)), *cert. denied*, 537 U.S. 1188 (2003). Accordingly, protection of organic farmers' economic interest would not support any injunction at all.

Moreover, these postulated economic harms have not been shown either to be *likely* or in any sense *irreparable*. Contrary to the district court's presumption that cross-pollination with RRA would "destroy the crops of those farmers who do not sell genetically engineered alfalfa," Pet.App.71a, the record makes clear that, regardless of any inadvertent cross-pollination, organic growers may market their crop as organic as long as they have taken the precautions required by the National Organic Program. Pet.App.263-64a, 413a-14a, 283a-84a, 262a-64a. And if meaningful cross-pollination occurs, it can be corrected

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goal of respondent Center for Food Safety is to "halt the approval, commercialization or release of any new genetically engineered crops until they have been thoroughly tested and found safe for human health and the environment," and "advocate [for] the containment and reduction of existing genetically engineered crops." *See* The Center for Food Safety, *GE Food*, http://truefoodnow.org/campaigns/genetically-engineered-foods/ (last visited Feb. 24, 2010). Respondents are certainly entitled to their opinion, but NEPA does not provide a forum for litigating policy disagreements.

within a single growing season using simple and well-established techniques. Pet.App.410a-11a. Moreover, there is no evidence that a single organic grower has ever lost organic certification or been unable to sell his crop as organic because of any cross-pollination with RRA. Similarly, there is no evidence in the record that any grower ever lost a single export sale due to cross-pollination with RRA.

Even if an organic farmer could not sell alfalfa with a small percentage of RRA as organic to a particular "zero tolerance" organic buyer, he still could sell the crop to other organic buyers or as conventional alfalfa to the 95% or more of the market that is not sensitive to the presence of genetically engineered traits. Pet.App.176a; *see also* Pet.App.383-84a (explaining diminished varietal purity meant only that seed crop could be sold as certified, rather than foundation seed). That might result in a loss of the premium value paid by certain organic buyers, but such a harm would be purely economic. Moreover, farmers have traditionally addressed such harms from neighboring crops at the local level, through grower organizations or through state law. There is no basis for concluding that the same system of practical and legal remedies would be inadequate to remedy any economic injury caused by cross-pollination between RRA and other alfalfa. And in the absence of such a showing, no injunction can issue. *See, e.g., eBay*, 547 U.S. at 391; *Weinberger*, 456 U.S. at 312.

The district court's opinion may also be read to suggest that the mere risk of RRA "contamination" could cause adjacent farmers a cognizable harm. It stated, for example, that "[f]or those farmers who choose to grow non-genetically engineered alfalfa, the *possibility* that their crops will be infected with the

engineered gene is tantamount to the elimination of all alfalfa." Pet.App.44a (emphasis added). Respondents' declarations likewise overwhelmingly relied upon the *fear* of cross-pollination, JA-380, 400-02, 404-05, 409-10, and the Ninth Circuit itself stated that respondents' request for injunctive relief was based on the "*fear* [of] cross-pollination of the new variety with other alfalfa." Pet.App.4a (emphasis added). But this Court has squarely held that the *risk* of harm is not itself a cognizable harm under NEPA. *See Metro. Edison Co.*, 460 U.S. at 775 ("*[R]isk* of an accident is not an effect on the physical environment. A risk is, by definition, unrealized in the physical world."); *id.* at 776 ("[C]ontentions of psychological health damage caused by risk [are not] cognizable under NEPA.").

Finally, even if they had alleged a cognizable irreparable harm, respondents never demonstrated that *they* were likely to suffer it. To obtain injunctive relief, a "plaintiff ... must establish ... that *he* is likely to suffer irreparable harm." *Winter*, 129 S. Ct. at 374 (emphasis added); *accord eBay*, 547 U.S. at 391 ("plaintiff must demonstrate ... that *it has suffered* an irreparable injury ...." (emphasis added)). That requirement is jurisdictional. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) ("[A] plaintiff must demonstrate standing for each claim he seeks to press ... [and] 'for each form of relief that is sought.'") (citation omitted). Respondents are neither a class of all alfalfa farmers, nor are they vested by law with authority to represent the interests of alfalfa itself, as the Lorax speaks for the trees. *See generally* Dr. Seuss, *The Lorax* (1971). They are only empowered to seek relief for irreparable injuries they themselves are likely to suffer, and they therefore cannot prevail by demonstrating that some farmer somewhere might be

forced to endure a low level of RRA in his fields. Pet.App.13a-14a, 71a.

3. The Ninth Circuit erred in affirming the injunction given the absence of record evidence of likely irreparable harm.

To the extent that the Ninth Circuit addressed the question of irreparable harm on the merits, it simply affirmed the injunction entered while the flawed *possibility*-of-harm test that this Court repudiated in *Winter* was still circuit precedent. The district court never required respondents to prove that irreparable harm was *likely*. *See* Pet.App.60a-79a. Indeed, the district court repeatedly relied upon the mere "*potential*" for irreparable harm. Pet.App.72a (emphasis added); *see also* Pet.App.75a. It never found a "likelihood" or "certainty" of such harm, only "potential"—*i.e.*, *possible*—harm. In fairness, the district court had no reason to go further because at the time Ninth Circuit law required only a possibility of harm. *Winter*, 129 S. Ct. at 374-75.

Winter was decided and brought to the Ninth Circuit's attention while this case was pending on rehearing. The Ninth Circuit's only response was to add a citation to *Winter* to a sentence—that it had *already written* before the Court's decision in *Winter*—affirming the district court's finding that irreparable harm was "sufficiently likely" to justify its injunction in this case. *Compare* Pet.App.13a *with* Pet.App.91a. But what was "sufficiently likely" before and after *Winter* in the Ninth Circuit are two very different things—hence this Court's grant of certiorari and reversal in *Winter* on that precise point. *Winter*, 129 S. Ct. at 375-76. The difference is dispositive here as well.

Indeed, the Ninth Circuit's error in affirming the injunction in this case was if anything more egregious than in *Winter*.

Far from establishing a *likelihood* of irreparable harm if the blanket injunction were not entered, the record evidence in this case is uncontradicted that the chances of any meaningful cross-pollination from RRA crops under APHIS's proposed stewardship measures would be exceedingly remote. Accordingly, under the standard reiterated in *Winter*—which limits injunctive relief to measures truly necessary to avoid likely irreparable harm, 129 S. Ct. at 375-76—the record compels the conclusion that the district court should have rejected respondents' request for a blanket injunction and entered an order adopting APHIS's proposed tailoring measures. Indeed, the record confirms that cross-pollination from either RRA hay or seed crops is exceedingly *un*likely.

a. Cross-pollination from the vast majority of RRA, grown for hay, is exceptionally unlikely, and there was no evidence that it has ever happened. Much like the injunction in *Winter*, the district court's injunction against RRA hay crops is supported by "no documented case of ... injury." 129 S. Ct. at 375. RRA was planted on 220,000 acres without any governmental restrictions for 21 months prior to the district court's injunction. Pet.App.408a-09a. Nearly all of that RRA was grown for hay, Pet.App.330a, and there is no evidence in the record of any cross-pollination from those RRA hay crops at any level to any conventional or organic crop in any location during that almost two-year period. Pet.App.277a-78a, 408a-09a. The absence of any such cross-pollination is fully consistent with declarations of experts in this case that, with APHIS's proposed interim measures in place, the

possibility of cross-pollination among adjacent hay crops would be approximately 2.5 in one million (0.00025%). Pet.App.160a, 229a-35a, 280a-81a, 378-80a.

As Dr. Putnam explained, the following independently unlikely events would *all* have to occur to permit successful hay-to-hay cross-pollination:

(1) *Both* the RRA and the conventional hay field must be allowed to flower—which is unlikely because hay farmers have strong financial incentives to harvest prior to significant flowering. JA-257, 347, 355-56, 483, 565; Pet.App.122a-23a, 128a, 280a-82a;

(2) The flowering of both fields must occur simultaneously—which is unlikely because different alfalfa varieties flower at different times and crops are often on different cutting/regrowth cycles. Pet.App.148a, 230a;

(3) In order to transfer pollen between fields, a sufficient number of bees must be present—which is unlikely because hay fields are not stocked with bees and feral bees are not generally attracted to hay fields because of the minimal flowering. Pet.App.129a-30a, 279a; JA-356, 483-84;

(4) The bees must actually move the pollen between the fields—which is unlikely because bees prefer other crops and rarely travel long distances between fields. Pet.App. 227a-28a, 231a, 279a;

(5) Any resulting seed must be permitted to mature—which is exceptionally unlikely because hay farmers routinely harvest prior to 10% bloom, which occurs *months* before seed maturation, and harvesting destroys maturing seed. Pet.App.130a, 280a-81a, 347a;

(6) The seed must successfully germinate—which is unlikely because mature alfalfa seeds are too heavy to be carried far by wind and autotoxicity will kill any seed that germinates near existing plants. Pet.App.130a, 279a.[15]

The only support that the district court offered for concluding that hay-to-hay cross-pollination was "sufficiently likely" to warrant its injunction was a concern that weather conditions "*could* prevent farmers from harvesting hay before 10% bloom." Pet.App.14a (emphasis added). But that concern is misplaced. A late harvest of RRA hay cannot lead to cross-pollination with other farmers' crops at any level (much less at a level causing them harm) unless the other unlikely events necessary for successful cross-pollination all occur *seriatim* thereafter. *Supra* at 43-44. The record demonstrates, moreover, that if an RRA farmer were to wait until after bloom to harvest his crop, adjoining conventional and organic hay growers could easily avoid any risk of cross-pollination by harvesting *their* crops in the remaining months prior to seed maturation (Pet.App.281a, 347a)—which is in their economic interest anyway because their hay also loses substantial economic value the longer it is permitted to grow after bloom. *Supra* at 12, 43.

Even assuming, however, that extraordinary weather conditions of Biblical dimensions, such as consecutive months of continuous rain, "could" so delay RRA and conventional farmers' harvests to permit meaningful levels of cross-pollination from RRA hay crops, neither the district court nor the Ninth Circuit ever purported to find that circumstance "likely," as

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15 *See* Pet.App.280a-83a; *see also* Pet.App.128a-30a, 178a-80a.

Winter requires. 129 S. Ct. at 375-76. Nor could they. The record compels the opposite conclusion.

Cross-pollination from RRA hay crops to conventional seed crops is also highly unlikely, for many of the same reasons. In a study conducted under conditions deliberately engineered to facilitate cross-pollination, Dr. Larry Teuber found that hay-to-seed cross-pollination of alfalfa varieties would "rarely [be] detected (0.00-0.05%)" with isolation distances of 350 feet, and "was very low (0.2%) at 150-300 ft." JA-484-90, 580-83; *see also* Pet.App.149a-50a, 278a-79a; *supra* at 13. No actual incidence of RRA hay-to-seed cross-pollination has ever been documented—even during the 21 months RRA was planted without any governmentally imposed restrictions. Pet.App.277a-78a, 408a-09a.

For these reasons, at a bare minimum, the blanket injunction must be vacated in so far as it prevents the planting of RRA hay crops.

b. Cross-pollination from the tiny percentage of RRA grown for seed is also unlikely. There was similarly no evidence to suggest that cross-pollination would be at all likely from the small percentage of RRA grown as seed crops under APHIS's stewardship measures. To the contrary, the government's and petitioners' experts attested that the probability would be "extremely low" or "de minimis." Pet.App.227a-30a, 234a-35a; *accord* Pet.App.226a-27a; JA-575-78; *see also* Pet.App.162a-63a, (seed-to-seed transmission would be no greater than 0.1% for seed fields stocked with leafcutter bees); Pet.App.178a (less than 0.03% for seed fields stocked with honey bees).

Those opinions are borne out by experience. Growers of different varieties of alfalfa seeds have

successfully used far shorter isolation distances to coexist for decades. Pet.App.382a-83a (noting certified seed growers use 165-330 feet isolation distances between varieties), Pet.App.216a; *see also Winter*, 129 S. Ct. at 376 ("find[ing] it pertinent that this is not a case in which the defendant is conducting a new type of activity with completely unknown effects on the environment"). And the evidence showed that seed-to-hay cross-pollination would be even less likely, since hay crops are generally harvested before any significant bloom, and weeks or months before any developing seed in a hay crop could mature. Pet.App.231a-32a, 281a, 347a, *supra* at 11-14. Indeed, there has never been a single reported incident of cross-pollination from RRA seed fields to the approximately 22 million acres of conventional and organic alfalfa hay crops grown domestically. Pet.App.408a-09a.

To the extent the district court addressed the likelihood of irreparable harm from RRA seed crops, it credited respondents' submissions that some "contamination has occurred" in certain seed crops under conditions "similar to" the stewardship measures proposed by APHIS. Pet.App.13a, 70a-71a. All of respondents' anecdotes about these supposed instances of "contamination" should have been excluded as inadmissible hearsay. *See supra* at 14-15. But in any event, none showed meaningful levels of cross-pollination under conditions remotely "similar to" APHIS's proposed stewardship measures. Only one of the instances of purported cross-pollination exceeded the contractually contemplated 1% tolerance level. JA-672-73; Pet.App.403a-07a. The other allegedly contaminated crops were sufficiently "pure" to be sold for full value under the contracts at issue—thus

precluding any harm to the (non-plaintiff) alfalfa grower. Pet.App.403a-07a. And the single instance where cross-pollination exceeded 1% involved a grower that planted a mere 200 feet away from another seed crop, Pet.App.406a; JA-673—*far* less separation than the 1500-feet to 3-mile isolation distances APHIS proposed for RRA seed crops, and indeed less separation than is recommended for the maintenance of conventional varieties, Pet.162a-63a.

Because respondents failed to prove any instances of meaningful cross-pollination from RRA seed crops under conditions similar to APHIS's proposed stewardship measures, and the record establishes that the potential for such cross-pollination is remote, the district court's blanket nationwide injunction must be vacated insofar as it bans the planting of RRA seed crops as well.

C. The Injunction Is Fatally Overbroad

The injunction is also fatally overbroad insofar as APHIS's proposed tailored relief—to which petitioners have not objected, *see* note 9, *supra*—would have eliminated any conceivable risk of harm. This Court has long held that a district court must narrowly tailor relief and that injunctions must be "no more burdensome to the defendant than necessary." *Califano*, 442 U.S. at 702; *see also Lewis v. Casey*, 518 U.S. 343, 357 (1996) ("The remedy must of course be limited to the inadequacy that produced the injury in fact that the plaintiff has established."); *Neb. HHS*, 435 F.3d at 330 ("We have long held that 'an injunction must be narrowly tailored to remedy the specific harm shown.'" (citation omitted)). Indeed, the goal of equitable analysis is to "arrive at a 'nice adjustment and reconciliation' between the competing claims."

Weinberger, 456 U.S. at 312 (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944)).

Nevertheless, the district court refused seriously to consider whether APHIS's proposed isolation distances and other stewardship measures would have sufficed to prevent irreparable harm. Indeed, the court was quite explicit about its refusal, stating "I am not going to get into the isolation distances." Pet.App.192a. Likewise, the Ninth Circuit utterly failed to engage on this issue: The court of appeals did not even mention what APHIS's proposed isolation distances were, let alone analyze their likely efficacy. *See* Pet.App.1a-20a. Both courts also failed to analyze meaningfully the differences between RRA hay and seed crops for cross-pollination purposes, even though the record shows that cross-pollination from the former is "orders of magnitude" less likely, Pet.App.279a, and the injunction against planting hay crops inflicted far more injury.

The lower courts' failure to consider APHIS's proposed mitigation measures was largely a product of their misguided notion that a blanket injunction was required pending completion of the EIS. But the lower courts also suggested that the proposed measures were beside the point because the government would not be able to enforce them (due to a lack of resources). *See* Pet.App.13a, 69a-70a. That reasoning turns the presumption of regularity on its head by assuming that governmental action will be *ineffective*. *See, e.g.*, *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001) ("[A] presumption of regularity attaches to the actions of government agencies ...."). Worse still, the district court's presumption of governmental incompetence was not focused on or limited to this particular agency or circumstance, but instead based on a broader

conception of the supposed futility of federal enforcement efforts: "[H]aving the authority and effectively using the authority are two different matters: the government has the authority to enforce the immigration laws, but unlawful entry into the United States still occurs." Pet.App.70a. The Ninth Circuit cited that misguided rationale with approval. Pet.App.13a.

Properly viewed, APHIS's proposed stewardship measures were more than sufficient to avert any likelihood of cross-pollination. Although respondents disagree with that, and argue that APHIS's proposed isolation distances of up to three miles would be insufficient, even they effectively concede that *some* isolation distance would prevent any possibility of cross-pollination. Indeed, their own submissions suggested that "5-mile" or "several miles" isolation distances would establish a "zero tolerance" standard. *See* Cert. Opp. at 9 n.6. Imposing "5-mile"/"several miles" isolation distances was therefore the limit of even *conceivably justifiable* injunctive relief.

The district court nevertheless rejected the use of isolation distances of any length and instead enjoined *all* RRA planting anywhere—whether seed or hay—even on farms that are *hundreds of miles* from any conventional or organic alfalfa. The blanket injunction it entered gratuitously harms farmers whose crops pose no conceivable risk. *See, e.g.*, Pet.App.221a ("[W]e are completely isolated from any conventional or organic seed production—the closest conventional seed operation is more than 300 miles away ...."); *see also* Pet.App.208a ("[T]here are only nine growers of organic hay in the entire state [of Nevada] and they are all in isolated areas ...."). And the Ninth Circuit's approval of this all-or-nothing approach is flatly

inconsistent with this Court's precedents and the extraordinary nature of injunctive relief.

II. PETITIONERS WERE ENTITLED TO AN EVIDENTIARY HEARING ON THE LIKELIHOOD OF IRREPARABLE HARM

Because the record does not support the finding of a likelihood of irreparable injury to any cognizable interest under APHIS's tailored injunction proposal, the district court was required to adopt APHIS's measures and reject respondents' request for a broad nationwide planting ban. The judgment of the Ninth Circuit should be reversed on those grounds and the case remanded with instructions to vacate the present injunction in favor of APHIS's more tailored proposal. To the extent that the record establishes any genuine dispute about the facts material to the issuance or breadth of the injunction to be entered, however, the courts below erred in denying petitioners an evidentiary hearing on those issues.[16]

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[16] The Court need not reach this issue if it concludes that the record does not support a finding of likely irreparable harm if APHIS's tailored injunction is imposed. However, because this issue is vitally important and recurring in entertaining requests for injunctive relief, the Court should make clear in its decision that a court may not disregard the traditional requirements for conducting an evidentiary hearing when it comes to considering a request for injunctive relief. *Cf. Winter*, 129 S. Ct. at 375-76 (addressing Ninth Circuit's "'possibility' standard" even though it was "not clear that articulating the incorrect standard affected the Ninth Circuit's analysis of irreparable harm").

A. The Evidentiary Hearing Is A Fundamental And Time-Honored Component Of Our Judicial System

The right to an evidentiary hearing with live witnesses and the opportunity for cross-examination is deeply rooted in our judicial system. For nearly a millennium, Anglo-American jurisprudence has resolved material factual disputes in the same way: trial-based, adversarial proceedings. *See, e.g.*, 3 William Blackstone, *Commentaries on the Laws of England* 349 (1st ed. 1768) (tracing trials back "so early as the laws of king Ethelred [king of England from 978-1016]" and observing "trial[s] ... ha[ve] been used time out of mind in this nation, and seem[] to have been co-eval with the first civil government thereof"). As this Court has observed, "[c]ertain principles," such as "confrontation and cross-examination," "have ancient roots" and "have remained relatively immutable in our jurisprudence." *Greene v. McElroy*, 360 U.S. 474, 496-97 & n.25 (1959) (tracing protections back "more than two thousand years" to Roman law); *see also* 5 *Wigmore on Evidence* §1367 (3d ed. 1940) ("For two centuries past, the policy of the Anglo-American system of evidence has been to regard the necessity of testing by cross-examination as a vital feature of the law."). Accordingly, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses." *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970).

The time-honored right to an evidentiary hearing extends equally to proceedings concerning requests for equitable relief. The Judiciary Act of 1789 expressly provided that "the mode of proof by oral testimony and examination of witnesses in open court shall be the

same ... in the trial of causes in equity ... as of actions at common law." Act of Sept. 24, 1789, ch. 20, §30, 1 Stat. 73, 88. And in 1912 Congress reaffirmed in the Federal Rules of Equity the necessity for common law trial procedures in equity suits. *See* Fed. Eq. R. 46 (1912); *accord* Neil Fox, Note, *Telephonic Hearings in Welfare Appeals: How Much Process Is Due?*, 1984 U. Ill. L. Rev. 445, 451 (1984). These trial-based requirements were preserved for all lawsuits with the merger of law and equity in the Federal Rules of Civil Procedural ("Federal Rules") in 1938.

The Federal Rules provide only a single mechanism for avoiding trial-based proceedings if the complaint states a basis for jurisdiction and a claim for which relief can be granted: summary judgment under Rule 56. *See* Fed. R. Civ. P. 56. And summary judgment may preempt the need for an evidentiary hearing only if there is "no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48, 250 (1986). That standard unquestionably applies equally to disputed issues of fact in the remedial phase of a proceeding, as Rule 56 provides that, where appropriate, summary judgment can be "rendered on liability alone." Fed. R. Civ. P. 56(d)(2); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 101 (D.C. Cir.) (en banc) ("A party has the right to judicial resolution of disputed facts not just as to the liability phase, but also as to appropriate relief."), *cert. denied*, 534 U.S. 952 (2001). Thus, absent waiver, district courts today must resolve factual disputes in all phases of a civil action the way common law courts always have, through live adversarial proceedings.

The overwhelming majority of federal circuits that have considered the issue have reached the same conclusion and held squarely that genuine disputes

about facts material to the entry or breadth of injunctive relief must be resolved through evidentiary hearings upon request. *See, e.g., Four Seasons Hotels & Resorts, B.V. v. Consorcio Barr, S.A.*, 320 F.3d 1205, 1211 (11th Cir. 2003); *In re Rationis Enters., Inc. of Panama*, 261 F.3d 264, 269 (2d Cir. 2001); *Microsoft*, 253 F.3d at 101-02; *Prof'l Plan Examiners of N.J., Inc. v. Lefante*, 750 F.2d 282, 288 (3d Cir. 1984); *United States v. McGee*, 714 F.2d 607, 613 (6th Cir. 1983).

In the leading modern case, *United States v. Microsoft*, the D.C. Circuit, sitting *en banc*, unanimously reversed a district court's imposition of an injunction without an evidentiary hearing. 253 F.3d at 101. The court grounded its analysis on the "cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings," and its recognition that "[a]ny other course would be contrary 'to the spirit which imbues our judicial tribunals prohibiting decision without hearing.'" *Id.* (quoting *Sims v. Greene*, 161 F.2d 87, 88 (3d Cir. 1947)). Following the Federal Rules and the common law's well-established procedures, the court held that "[o]ther than a temporary restraining order, *no injunctive relief may be entered without a hearing.*" *Id.* (emphasis added).

B. The Ninth Circuit Erred In Holding That Petitioners Could Be Deprived Of An Evidentiary Hearing Here

The Ninth Circuit "generally" agrees with the other courts of appeals on the necessity for an evidentiary hearing on the availability of injunctive relief where there are disputed issues of material fact. *See Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988) ("Generally the entry or continuation of an

injunction requires a hearing. Only when the facts are not in dispute, or when the adverse party has waived its right to a hearing, can that significant procedural step be eliminated." (quotations omitted)). And it purported to reaffirm that position in this case. *See* Pet.App.17a. But the court nonetheless held that an evidentiary hearing was not required here for two reasons: (1) there were no "material issues of fact" in dispute and (2) cases arising under NEPA differ from the "'normal injunctive setting'" because, in contrast to "typical" injunctions of "indefinite duration," NEPA-based injunctions are temporary. Pet.App.17a-18a. Neither of those justifications withstands scrutiny.[17]

The first rationale—the purported absence of "material issues of fact"—is inextricably tied to the Ninth Circuit's erroneous view that an injunction can

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[17] In its amended opinion, the Ninth Circuit suggested for the first time that an "evidentiary hearing" may be deemed to have taken place because FGI's President, Mark McCaslin, was permitted to address the court with unsworn statements from counsel's table. Pet.App.19a-20a; *supra* at 13 n.6. But the Ninth Circuit nevertheless also retained its—correct—statement from its original opinion that "[w]hat the district court did *not* do was to hold an additional evidentiary hearing to resolve the very disputes over the risk of environmental harm that APHIS would have to consider in the EIS." Pet.App.20a (emphasis added). And the suggestion that a few questions directed to a party at counsel's table during an argument on a dispositive motion qualifies as an evidentiary hearing is profoundly misguided. Indeed, as Judge Smith observed in dissent, the oral argument to which the majority pointed "f[ell] far short of the standards we have articulated for [an evidentiary] hearing." Pet.App.23a. No witnesses were sworn in, petitioners were not permitted to call their own witnesses or cross-examine any adverse witnesses/declarants, the court did not rule on petitioners' evidentiary objections, and the only questions asked of McCaslin were tendered by the district court, not counsel. JA-552-54.

issue for a NEPA violation without proof of a likelihood of irreparable harm. The Ninth Circuit appreciated that the parties disagreed about the likelihood of irreparable harm under APHIS's proposed injunction, Pet.App.9a, but it did not believe that factual disputes needed to be resolved to affirm the district court's injunction. In other words, it did not believe that the question of the likelihood of irreparable harm under a narrower injunction was *legally* material to the propriety of the blanket injunction entered by the district court. As explained above, that aspect of the Ninth Circuit's reasoning is directly at odds with this Court's holdings in *Winter*, *Amoco*, and *Weinberger*.

The Ninth Circuit's second reason for approving the district court's denial of an evidentiary hearing—the "temporary" nature of NEPA-based injunctions—is equally untenable. The limited tenure of the permanent injunction in this case is hardly exceptional. All injunctions are by their nature temporary. *See, e.g.*, *Bd. of Educ. of Okla. City Pub. Schs. v. Dowell*, 498 U.S. 237, 248 (1991) (holding that injunctions, even for constitutional violations, "are not intended to operate in perpetuity"). Indeed, federal courts are *supposed to facilitate* the expiration of their injunctions—despite their styling as being "permanent." *See, e.g.*, *Horne v. Flores*, 129 S. Ct. 2579, 2595-96 (2009) (holding that federal courts have an obligation to see that authority is "'returned *promptly* to the State and its officials,'" and that once a violation has been remedied, "continued enforcement of the order is not only unnecessary, *but improper*") (emphasis added) (citation omitted)).

More fundamentally, the right to a hearing no more hinges on the expected duration of an injunction than it does on the expected amount of legal damages. Indeed, the vast majority of courts of appeals recognize that

the right to a hearing extends equally to disputes over *preliminary* injunctions, which are by definition temporary. *See Four Seasons Hotels*, 320 F.3d at 1211; *In re Rationis Enters.*, 261 F.3d at 269; *Microsoft*, 253 F.3d at 101-02; *Lefante*, 750 F.2d at 288; *see also* 13 James Wm. Moore, *Moore's Federal Practice* §65.21[4] (3d ed. 2009) ("A hearing on the merits of the preliminary injunction is thus usually required only when a dispute exists between the parties as to the material facts."). *But see Campbell Soup Co. v. Giles*, 47 F.3d 467, 470 (1st Cir. 1995) (rejecting "'categorical rules'" of other circuits and instead "'balancing between speed and practicality versus accuracy and fairness'" (citation omitted)).

Regardless of its expected duration, an injunction is an "extraordinary and drastic remedy." *Munaf*, 128 S. Ct. at 2219 (quotation omitted). Even short-term injunctions can impose great costs. Indeed, the nationwide injunction issued in this case was predicted to cause roughly one quarter of a billion dollars in damages in the first two years alone. Due to the "drastic" nature of injunctions, this Court has long insisted that courts carefully adhere to the time-honored standards governing the entry of such relief. *See, e.g.*, *Winter*, 129 S. Ct. at 374-75; *eBay, Inc.*, 547 U.S. at 391-392; *Amoco*, 480 U.S. at 542; *Weinberger*, 456 U.S. at 311-12. And faithful adherence to the ages-old requirement of an evidentiary hearing to resolve disputed issues of material fact is no less important in determining whether injunctive relief is warranted. In upholding the injunction at issue, the Ninth Circuit fundamentally disregarded both the traditional requirements for equitable relief and the necessity of

an evidentiary hearing to resolve disputed issues of material fact bearing on those requirements.[18]

CONCLUSION

The judgment of the court of appeals should be reversed, and the case remanded with instructions to vacate the district court's injunction and enter APHIS's proposed remedy in its place.

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[18] The government did not request an evidentiary hearing and, in opposing certiorari, stated that it "does not believe one was necessary." Fed.Opp.14. But the government has not argued that there were no disputed issues of material fact—the customary trigger for an evidentiary hearing. Instead, it advances the general notion that "the granting of injunctive relief in a suit challenging agency action under the Administrative Procedure Act (APA) presents different considerations than the granting of relief in private litigation." Fed.Opp.16. The government may well be right that resolution of disputed factual issues implicating an administrative record raises additional considerations. But the government by no means has a monopoly on deciding when an evidentiary hearing is warranted. In this case, the facts relevant to the likelihood of irreparable harm were developed after and outside of the administrative record, which focused only on the need for an EIS. And petitioners—who are parties to this litigation after having successfully intervened to defend the agency's proposed remedy—properly requested and were entitled to an evidentiary hearing before the injunction at issue was entered.

Respectfully submitted,

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CONSTITUTION OF THE UNITED STATES

Amendment V

No person shall . . . be deprived of life, liberty, or property, without due process of law . . . .

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 55. NATIONAL ENVIRONMENTAL POLICY SUBCHAPTER I. POLICIES AND GOALS

42 U.S.C. § 4332

§ 4332. Cooperation of agencies; reports; availability of information; recommendations; international and national coordination of efforts

The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall—

(A) utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking which may have an impact on man's environment;

(B) identify and develop methods and procedures, in consultation with the Council on Environmental Quality established by subchapter II of this chapter, which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations;

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

(i) the environmental impact of the proposed action,

(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,

(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section 552 of title 5, and shall accompany the proposal through the existing agency review processes;

(D) Any detailed statement required under subparagraph (C) after January 1, 1970, for any major Federal action funded under a program of grants to States shall not be deemed to be legally insufficient solely by reason of having been prepared by a State agency or official, if:

(i) the State agency or official has statewide jurisdiction and has the responsibility for such action,

(ii) the responsible Federal official furnishes guidance and participates in such preparation,

(iii) the responsible Federal official independently evaluates such statement prior to its approval and adoption, and

(iv) after January 1, 1976, the responsible Federal official provides early notification to, and solicits the views of, any other State or any Federal land management entity of any action or any alternative thereto which may have significant impacts upon such State or affected Federal land management entity and, if there is any disagreement on such impacts, prepares a written assessment of such impacts and views for incorporation into such detailed statement.

The procedures in this subparagraph shall not relieve the Federal official of his responsibilities for the scope, objectivity, and content of the entire statement or of any other responsibility under this chapter; and further, this subparagraph does not affect the legal sufficiency of statements prepared by State agencies with less than statewide jurisdiction.[1]

(E) study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources;

(F) recognize the worldwide and long-range character of environmental problems and, where consistent with the foreign policy of the United States, lend appropriate support to initiatives, resolutions, and programs designed to maximize international

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[1] So in original. The period probably should be a semicolon.

cooperation in anticipating and preventing a decline in the quality of mankind's world environment;

(G) make available to States, counties, municipalities, institutions, and individuals, advice and information useful in restoring, maintaining, and enhancing the quality of the environment;

(H) initiate and utilize ecological information in the planning and development of resource-oriented projects; and

(I) assist the Council on Environmental Quality established by subchapter II of this chapter.

TITLE 7. AGRICULTURE

SUBTITLE B. REGULATIONS OF THE DEPARTMENT OF AGRICULTURE

CHAPTER III. ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 340. INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

7 C.F.R. § 340.0

§ 340.0 Restrictions on the introduction of regulated articles.

(a) No person shall introduce any regulated article unless the Administrator is:

(1) Notified of the introduction in accordance with § 340.3, or such introduction is authorized by permit in accordance with § 340.4, or such introduction is conditionally exempt from permit requirements under § 340.2(b); and

(2) Such introduction is in conformity with all other applicable restrictions in this part.[1]

(b) Any regulated article introduced not in compliance with the requirements of this part shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary to prevent the introduction of such plant pests.[2]

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[1] Part 340 regulates, among other things, the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests. The introduction into the United States of such articles also may be subject to other regulations promulgated under the Plant Protection Act (7 U.S.C. 7701-7772) and found in 7 CFR parts 319, 330, and 360. For example, under regulations promulgated in "Subpart-Nursery Stock, Plants, Roots, Bulbs, Seeds, and Other Plant Products" (7 CFR 319.37-3), a permit is required for the importation of certain classes of nursery stock whether such stock is genetically engineered or not. Accordingly, individuals should refer to those regulations before importing any nursery stock.

[2] An inspector may hold, seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of plants, plant pests, or other articles in accordance with sections 411, 412, 421, and 434 of the Plant Protection Act (7 U.S.C. 7711, 7712, 7731, and 7754).

Title 7. Agriculture

Subtitle B. Regulations of the Department of Agriculture

Chapter III. Animal and Plant Health Inspection Service, Department of Agriculture

Part 340. Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests

7 C.F.R. § 340.6

§ 340.6 Petition for determination of nonregulated status.

* * *

(d) Administrative action on a petition.

* * *

(3) The Administrator shall, based upon available information, furnish a response to each petitioner within 180 days of receipt of a completed petition. The response will either:

(i) Approve the petition in whole or in part; or

(ii) deny the petition.

The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public petition file in the offices of APHIS and notice of availability published in the Federal Register.

* * *

TITLE 40. PROTECTION OF ENVIRONMENT
CHAPTER V. COUNCIL ON ENVIRONMENTAL QUALITY
PART 1508. TERMINOLOGY AND INDEX

40 C.F.R. § 1508.9

§ 1508.9 Environmental assessment.

Environmental Assessment:

(a) Means a concise public document for which a Federal agency is responsible that serves to:

(1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact.

(2) Aid an agency's compliance with the Act when no environmental impact statement is necessary.

(3) Facilitate preparation of a statement when one is necessary.

* * *

TITLE 40. PROTECTION OF ENVIRONMENT
CHAPTER V. COUNCIL ON ENVIRONMENTAL QUALITY
PART 1508. TERMINOLOGY AND INDEX

40 C.F.R. § 1508.13

§ 1508.13 Finding of no significant impact.

Finding of no significant impact means a document by a Federal agency briefly presenting the reasons why an action, not otherwise excluded (§ 1508.4), will not have a significant effect on the human environment and for which an environmental impact statement therefore will not be prepared. It shall include the environmental assessment or a summary of it and shall note any other environmental documents related to it (§ 1501.7(a)(5)). If the assessment is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference.

RESPONDENT'S BRIEF

Supreme Court, U.S.
FILED
MAR 2 - 2010
OFFICE OF THE CLERK

No. 09-475

In the Supreme Court of the United States

MONSANTO COMPANY, ET AL., PETITIONERS

v.

GEERTSON SEED FARMS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS

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QUESTIONS PRESENTED

This case arose out of the decision of the Animal and Plant Health Inspection Service (APHIS) to deregulate a kind of genetically engineered alfalfa, based on APHIS's determination that the alfalfa did not present a plant pest risk. Petitioner Monsanto owns the intellectual property rights to the subject alfalfa and licenses the technology exclusively to co-petitioner Forage Genetics International, LLC. After finding that APHIS had not adequately analyzed the environmental impacts of its deregulation action under the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*, the district court entered, and the court of appeals affirmed, a permanent injunction requiring APHIS to prohibit further planting of the subject alfalfa pending the agency's completion of an Environmental Impact Statement and final decision regarding deregulation. The questions presented are:

1. Whether the court of appeals erred in affirming a permanent nationwide injunction based on a legal standard that presumed irreparable harm.

2. Whether the court of appeals erred in determining that the district court did not abuse its discretion when it declined petitioners' request for an evidentiary hearing on the scope of the permanent injunctive relief.

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In the Supreme Court of the United States

No. 09-475

MONSANTO COMPANY, ET AL., PETITIONERS

v.

GEERTSON SEED FARMS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS

OPINIONS BELOW

The amended opinion of the court of appeals (Pet. App. 1a-26a) is reported at 570 F.3d 1130. The opinion of the district court (Pet. App. 60a-79a) is unreported.

JURISDICTION

The amended judgment of the court of appeals was entered and a petition for rehearing was denied on June 24, 2009 (Pet. App. 104a-107a). The petition for a writ of certiorari was granted on January 15, 2010. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATEMENT

1. The Plant Protection Act (PPA), 7 U.S.C. 7701 *et seq.*, provides a statutory framework for the regulation of plant pests by the Secretary of Agriculture. The PPA

states that "no person shall import, enter, export, or move in interstate commerce any plant pest," unless the action is "authorized under general or specific permit" and is in accordance with regulations issued by the Secretary to prevent the "introduction of plant pests into the United States or the dissemination of plant pests within the United States." 7 U.S.C. 7711(a). Congress enacted the PPA based on its finding that "the smooth movement of enterable plants, plant products, biological control organisms, or other articles into, out of, or within the United States is vital to the United State[s'] economy and should be facilitated to the extent possible." 7 U.S.C. 7701(5). Congress further determined, however, that the Secretary should facilitate such movement "in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests and noxious weeds." 7 U.S.C. 7701(3).

The Secretary of Agriculture has delegated his responsibilities under the PPA to the Animal and Plant Health Inspection Service (APHIS). 7 C.F.R. 2.22(a), 2.80(a)(36). APHIS has promulgated regulations governing, *inter alia*, the introduction (*i.e.*, importation, interstate movement, or release into the environment, see 7 C.F.R. 340.1) of "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests," 7 C.F.R. 340.0(a)(2) n.1. See 7 C.F.R. Pt. 340. Such items are referred to in the regulations as "regulated article[s]." 7 C.F.R. 340.1.

The regulations provide that a regulated article may be introduced for field testing purposes pursuant to a notification process and subject to specified restrictions to protect against dissemination of the article. See

7 C.F.R. 340.3. The regulations also provide for the issuance of permits for the introduction of a regulated article. See *ibid.* The PPA and its implementing regulations authorize any person to petition APHIS for a determination that an article does not present a plant pest risk and therefore should not be regulated under 7 C.F.R. Pt. 340. 7 U.S.C. 7711(c)(2); 7 C.F.R. 340.6(a). If APHIS determines, "based upon available information," that the regulated article should not be regulated under Part 340, it will approve the petition, either in whole or in part. 7 C.F.R. 340.6(d)(3). The PPA mandates that the Secretary's ultimate decision to approve or deny the petition must be based on "sound science." 7 U.S.C. 7701(4).

2. Congress enacted the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, in order to foster better decisionmaking by agencies and more informed public participation with respect to agency actions that affect humans and the human environment. See 42 U.S.C. 4321; 40 C.F.R. 1501.1(c). NEPA requires that, whenever a federal agency proposes a "major Federal action[] significantly affecting the quality of the human environment," the agency must examine the reasonably foreseeable environmental effects of the proposed action and inform the public about those effects. 42 U.S.C. 4332(2)(C); 40 C.F.R. Pt. 1508; see *BG&E* v. *NRDC*, 462 U.S. 87, 97 (1983). In so doing, the agency must prepare a "detailed statement" of the environmental impact of the proposed action—an "environmental impact statement" (EIS)—the requirements for which are set out in regulations issued by the Council on Environmental Quality (CEQ). 42 U.S.C. 4332(2)(C); 40 C.F.R. Pts. 1502, 1508.

The regulations permit an agency to comply with NEPA by preparing an "environmental assessment" (EA) in lieu of an EIS in certain circumstances. 40 C.F.R. 1501.4. The regulations define an EA as a "concise public document" that briefly describes the need for, alternatives to, and environmental impacts of the proposed federal action. 40 C.F.R. 1508.9. If the agency determines, based on the EA, that the proposed federal action will not significantly affect the quality of the human environment, it then makes a "[f]inding of no significant impact" (FONSI), 40 C.F.R. 1508.13, and it need not prepare an EIS, 40 C.F.R. 1501.3. If the agency determines that the proposed action will significantly affect the quality of the environment, it must prepare an EIS. 40 C.F.R. Pt. 1502; see *DOT* v. *Public Citizen*, 541 U.S. 752, 757-758 (2004).

NEPA "does not mandate particular results, but simply prescribes the necessary process." *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989). NEPA's "mandate to the agencies is essentially procedural" and is designed "to insure a fully informed and well-considered decision" on the part of the federal agency. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978).

3. This case concerns "Roundup Ready alfalfa" (RRA), an alfalfa crop that was genetically engineered by petitioner Monsanto Company (Monsanto) to tolerate glyphosate, the active ingredient in the herbicide Roundup. Pet. App. 5a. RRA was genetically engineered to be glyphosate-tolerant by inserting into the alfalfa genome a gene that codes for a particular enzyme. J.A. 348. The gene is from a common soil bacterium (*Agrobacterium* sp. strain CP4), and was introduced via an *Agrobacterium*-mediated transformation

protocol that has been used to introduce specific genes into plant genomes for more than twenty years. *Ibid.* APHIS initially classified RRA as a regulated article under the PPA. Pet. App. 5a.

Alfalfa is a perennial herbaceous legume that is pollinated by insects, usually honeybees or leafcutter bees. J.A. 346-347. Nearly all (99%, see Pet. App. 321a) of the alfalfa grown in this country is grown for consumption by livestock as hay or forage. J.A. 346. Alfalfa is also grown for seed. Most of that seed is used to produce alfalfa plants for hay or forage, although a small amount is grown for human consumption in the form of alfalfa sprouts. J.A. 346-347. More than 22 million acres of alfalfa are harvested in the United States every year. J.A. 446. The States that produce the most alfalfa are located in the Midwest and West, including California, South Dakota, Wisconsin, Idaho, Minnesota, and Iowa. *Ibid.* Alfalfa hay is primarily sold in three major markets: for dairy cattle (the predominant market), beef cattle, and horses. J.A. 447-448. The market for alfalfa seed is far smaller in acreage and more localized in western States. J.A. 447.

Depending on the needs of the grower and the climate, alfalfa can be planted in the Spring or Fall. Once established, an alfalfa field can be mowed three to four times per year and remain productive for a number of years. J.A. 346-347. Within a field, the plant is often rotated with other crops, both because alfalfa improves the nitrogen content of the soil in which it is planted and because alfalfa exhibits autotoxicity, meaning that alfalfa seeds do not germinate well in established alfalfa fields. J.A. 347.

The management of weeds in alfalfa fields can be expensive, labor intensive, and sometimes complicated.

J.A. 182. Alfalfa growers often use pre-emergent herbicides, which prevent weed seeds from germinating, but a pre-emergent herbicide must be applied in all areas of a field to be effective. *Ibid.* By growing RRA, which is tolerant of glyphosate, growers may instead apply a glyphosate herbicide only after weeds have germinated and only in areas where weeds actually appear. *Ibid.*

APHIS first authorized the field testing of RRA in 1998. J.A. 348. In 1999 and 2000, Monsanto and FGI submitted design protocols to APHIS describing how field trials of RRA would be managed in order to comply with the performance standards that govern all genetically engineered crops authorized by APHIS for field trials. *Ibid.* Those standards require that the genetically engineered plants be confined effectively and that they be discarded after the conclusion of the field trial. *Ibid.* The protocols submitted by Monsanto and FGI included either (1) the maintenance of a buffer zone of at least 900 feet between RRA and other alfalfa, (2) the confinement of flowering plants to cages in order to bar access by pollinators, or (3) the mowing of plantings to prevent the development of flower buds. *Ibid.* In addition, the protocols required the cleaning after use of any farm equipment used on RRA that could have retained its reproductive parts. J.A. 349. The protocols further required that RRA be destroyed with herbicide when the trials ended, and that the plant debris be incorporated into the soil by disking. *Ibid.* Finally, fields planted with RRA were required to be labeled and monitored for one growing season after the termination of the trial. *Ibid.* APHIS ultimately authorized 297 field trials over the course of approximately eight years prior to its decision to deregulate RRA. J.A. 348.

4. In 2004, petitioners submitted to APHIS a petition requesting non-regulated status for RRA under the PPA. Pet. App. 5a. On November 24, 2004, after completing a draft EA, APHIS published a notice in the *Federal Register* (1) informing the public of APHIS's receipt of the petition, (2) making the EA available for public comment, and (3) soliciting public comment on whether RRA presents a plant pest risk. See *id.* at 6a; 69 Fed. Reg. 68,300-68,301.

On June 27, 2005, APHIS published in the *Federal Register* a notice that it had prepared a final EA regarding the proposal to deregulate RRA and had "reached a finding of no significant impact." 70 Fed. Reg. 36,917-36,919. APHIS issued the FONSI after analyzing "data submitted by Monsanto/FGI, a review of other scientific data, field tests of the subject alfalfa, and comments submitted by the public." *Id.* at 36,918. In its deregulation decision, APHIS explained its determinations that RRA: (1) exhibits no plant pathogenic properties; (2) exhibits no characteristics that would cause it to be more weedy than other alfalfa; (3) is unlikely to increase the weediness potential of other species; (4) will not damage raw or processed agricultural commodities; (5) should not damage or harm organisms beneficial to agriculture; and (6) should not reduce the ability to control pests or weeds in alfalfa or other crops. *Id.* at 36,918-36,919. On the basis of its FONSI, APHIS concluded that it did not need to prepare an EIS, and it deregulated RRA. Pet. App. 7a.

5. In February 2006, approximately eight months after APHIS rendered its decision to deregulate RRA, Geertson Seed Farms and others (hereinafter respondents) filed suit against the Secretary of Agriculture and other federal officials (collectively, APHIS) alleging

violations of NEPA, the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531 *et seq.*, and the PPA. Pet. App. 7a, 27a. Respondents did not seek preliminary injunctive relief prior to the court's determination of the merits of their claims, and RRA therefore was commercially available for planting based on its deregulated status beginning in June 2005. *Id.* at 55a, 58a; J.A. 350.

On cross-motions for summary judgment, the district court held that APHIS had violated NEPA in failing to prepare an EIS. Pet. App. 37a-53a. The court found that APHIS's EA was insufficient in two respects: (1) it did not adequately consider the potential for gene transmission between RRA and non-genetically engineered alfalfa; and (2) it did not adequately consider the potential for the development of glyphosate-resistant weeds. *Id.* at 7a-8a, 32a-53a. The district court declined to reach respondents' ESA and PPA claims. *Id.* at 51a.

Following the district court's decision on the merits, petitioners moved to intervene as defendants on the question of remedy. Pet. App. 8a. The district court granted their motions, agreeing to give them the opportunity "to present evidence to assist the court in fashioning the appropriate scope of whatever relief is granted." *Id.* at 54a (citing *Forest Conservation Council* v. *USFS*, 66 F.3d 1489, 1496 (9th Cir. 1995)). The court received written evidentiary submissions from all parties and heard several hours of oral argument, on the basis of which it issued a preliminary injunction. *Id.* at 63a; see *id.* at 54a-59a.

APHIS proposed a remedy under which it would, in addition to preparing an EIS, impose six restrictions on the planting of RRA and on the handling of RRA seed pending the completion of the EIS. Pet. App. 184a-187a; see J.A. 376-378. APHIS's proposed restric-

tions included: (1) mandatory isolation distances between RRA and conventional or organic alfalfa seed production fields to mitigate any potential pollen flow between the two; (2) mandatory harvesting conditions for RRA fields to minimize cross-pollination in areas where alfalfa seed is produced; (3) a requirement that planting and harvesting equipment be cleaned after contact with RRA prior to its use on non-genetically engineered alfalfa; (4) identification and handling requirements for RRA seed applicable before and after harvest; (5) a prohibition on the use of RRA for livestock grazing purposes or in mixed grass pastures; and (6) a requirement that all RRA seed producers and hay growers be under contract with either Monsanto or FGI and that their contracts require compliance with the first five conditions. See J.A. 439-445. APHIS explained the bases for these conditions in the first and second declarations of Dr. Neil Hoffman, Director of the Environmental Risk Analysis Division of APHIS's Biotechnology Regulatory Services (BRS), and the exhibits attached thereto. J.A. 345-365, 436-542. In setting forth the scientific underpinnings of APHIS's proposed conditions, the Director noted that "BRS has many years of experience regulating [RRA]" and "ha[d] previously granted nonregulated status to other GE [genetically engineered] glyphosate-tolerant crops, including corn, cotton, soybean, canola and sugarbeet." J.A. 347, 348.

Instead of adopting APHIS's suggested limitations, the district court issued a preliminary injunction on March 12, 2007, vacating APHIS's deregulation determination and enjoining all planting of RRA and all sales of RRA seed beginning March 30, 2007. Pet. App. 8a, 54a-59a. The court cited *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), for the proposi-

tion that, "[i]n the run of the mill NEPA case, the contemplated project, whether it be a new dam or a highway extension, is simply delayed until the NEPA violation is cured," although in "unusual circumstances" an injunction "may be withheld or, more likely, limited in scope." Pet. App. 55a. The court noted that this was not a run of the mill case in certain respects because some alfalfa growers had already purchased and planted RRA in reliance on APHIS's deregulation decision. *Id.* at 8a, 55a. The court did not require those growers to remove or destroy their already-planted RRA; the court also allowed growers who had already purchased RRA seed at the time of its order to plant such seed prior to March 30, 2007. *Id.* at 8a, 55a-58a. In other respects, however, the court concluded that this case was an ordinary NEPA case, and that neither APHIS nor petitioners had identified any "unusual circumstances" that would lead the court to permit an increase in the number of acres planted with RRA while the court considered the appropriate scope of permanent injunctive relief. *Id.* at 56a-57a. The court noted that it would consider "whatever additional evidence [petitioners] wish to provide," allow APHIS the opportunity to present additional evidence, and allow respondents to make their own submission before fashioning permanent injunctive relief. *Id.* at 58a-59a.

The parties then submitted evidence, including declarations, concerning the appropriate scope of permanent injunctive relief. Pet. App. 9a, 64a. The court entered a permanent injunction on May 3, 2007. *Id.* at 60a-79a. The court ordered APHIS to prepare an EIS and enjoined all planting of RRA from March 30, 2007, until the completion of the EIS. *Id.* at 79a. In its order, the court acknowledged that petitioners had "requested

an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed, as well as to resolve disputes with plaintiffs' witnesses." *Id.* at 67a. The court denied that request, reasoning that to make the findings requested by petitioners would be tantamount "to engag[ing] in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." *Id.* at 68a; see *id.* at 68a-69a.

The district court also noted that APHIS had not submitted evidence concerning whether, and to what extent, its proposed interim conditions would be followed. Pet. App. 69a-70a. The court criticized the efficacy of particular proposed restrictions in eliminating the possibility of gene flow, noting that weather conditions might prevent farmers from always harvesting as contemplated by APHIS's proposal. *Id.* at 70a-71a. The court stated that it had explained in its ruling on the merits of the NEPA issue that "contamination of organic and conventional alfalfa crops with the genetically engineered gene has occurred and defendants acknowledge as much. Such contamination is irreparable environmental harm." *Id.* at 71a; see *id.* at 70a-71a. The court concluded that the harm to "farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa." *Id.* at 71a.

6. a. APHIS and petitioners appealed on the ground that the permanent injunction was overly broad. Pet. App. 10a. Petitioners further argued that the district court erred by denying their request for an evidentiary hearing. *Id.* at 16a. No appellant challenged the

district court's merits determination that APHIS's NEPA analysis was insufficient. *Id.* at 5a.

The court of appeals initially affirmed entry of the permanent injunction in an opinion dated September 2, 2008. Pet. App. 82a-103a. Following the filing of a petition for rehearing and rehearing en banc by petitioners, the court issued an amended opinion on June 24, 2009, *id.* at 1a-26a, and simultaneously denied the petition for rehearing en banc, *id.* at 104a-107a.

The court of appeals rejected the contention that the district court had erred in issuing the permanent injunction because it had improperly presumed irreparable injury to respondents. Pet. App. 10a-16a. In the court of appeals' view, "the record demonstrates that the district court applied the traditional four-factor test" for the issuance of an injunction, as "required by" *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006). Pet. App. 13a; *id.* at 10a-16a. The court noted that the district court had found that gene contamination of organic and conventional alfalfa had occurred while petitioners had contractual obligations in place that were similar to the mitigation measures proposed by APHIS, and that such contamination constituted irreparable harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed. *Id.* at 13a-14a. The court also concluded that the district court adequately considered the interests of both petitioners and the public. *Id.* at 14a-15a. In upholding the scope of the injunction, the court of appeals rejected the government's argument that the district court should have deferred to APHIS's proposed interim measures. *Id.* at 15a-16a.

Finally, the court rejected petitioners' argument that the district court erred in declining to hold an evi-

dentiary hearing involving live testimony before issuing the permanent injunction. Pet. App. 16a-20a. The court stated that a district court should generally hold such a hearing absent waiver by the adverse party. *Id.* at 17a. But the court of appeals explained that the district court in this case "did not believe defendants had established any material issues of fact that were in dispute in the case before the court," but rather "viewed the disputed matters to be issues to be more properly addressed by the agency in the preparation of an EIS." *Id.* at 17a-18a.

The court of appeals observed in this regard that the injunction at issue was similar to the one in *Idaho Watersheds*—which the court of appeals also upheld without an evidentiary hearing, 307 F.3d at 830-831—because the injunction will be in effect only until APHIS completes an EIS and provides the parties with an opportunity to participate in further proceedings regarding the scope of permanent measures. Pet. App. 17a-19a. The court noted as well that the government did not contend that an evidentiary hearing was required, perhaps to avoid the duplicative inquiries by the district court and the agency of the sort the court of appeals had described in *Idaho Watersheds*. *Id.* at 19a. Finally, the court disagreed with the dissent on the antecedent issue of whether the district court had failed to hold any evidentiary hearing at all, noting that the court had held one hearing on the NEPA violation, held two hearings on the scope of injunctive relief (which included some questioning by the court of petitioner Forage Genetics' president), and reviewed extensive documentary submissions. *Id.* at 19a-20a.

b. Judge Smith dissented on the issue of whether the district court should have conducted an evidentiary

hearing before issuing the permanent injunction. Pet. App. 20a-26a. He would have held that, under Federal Rule of Civil Procedure 65, a district court must hold an evidentiary hearing unless the material facts are undisputed or the adverse party waives its right to such a hearing. Pet. App. 20a-21a (citing *Charlton* v. *Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). Judge Smith found that neither exception applied, and dismissed as insignificant APHIS's failure to request an evidentiary hearing given that petitioners had requested one. *Id.* at 21a-22a.

7. Pursuant to the district court's order, APHIS has been preparing an EIS related to the petition to deregulate RRA. On December 14, 2009, APHIS announced the availability for public review of a nearly 200-page draft EIS, which addresses, *inter alia*, the potential for gene flow from RRA to conventional and organic alfalfa, as well as the potential for an increase in glyphosate-resistant weeds. USDA, *Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status Draft Environmental Impact Statement* (Nov. 2009), http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf (draft EIS); *USDA Seeks Public Comment on Draft Environmental Impact Statement for Genetically Engineered Alfalfa* (Dec. 14, 2009), http://www.aphis.usda.gov/newsroom/content/2009/12/ printable/alfalfa_brs.pdf (press release). APHIS extended the initial 60-day comment period, which commenced on December 18, 2009, the date of publication of the notice of availability of the draft EIS in the *Federal Register*. 74 Fed. Reg. 67,206. The comment period will now close on March 3, 2010. 75 Fed. Reg. 8299-8300 (2010).

SUMMARY OF ARGUMENT

The issuance of a permanent injunction in this case was improper. The district court failed to find either that respondents had suffered or were likely to suffer irreparable harm or that legal remedies would be inadequate to compensate any harm respondents might suffer. Instead, the district court presumed that irreparable injury had resulted or would result from APHIS's failure to comply with the procedural requirements of NEPA. But this Court has repeatedly held that the mere fact of a statutory violation by a government agency does not establish irreparable injury. The Court has emphasized that plaintiffs challenging administrative action must satisfy the traditional four-factor test before a district court may enter an injunction.

As a result of the lower courts' error, there is a nationwide injunction in place that is not supported by the equities of this case. The injunction eliminates a choice for growers and consumers nationwide and intrudes on APHIS's regulatory role. APHIS deregulated RRA in furtherance of its mission under the PPA, and the district court did not find a substantive violation of the PPA. Nor did respondents submit any evidence that their alfalfa crops had been cross-pollinated by the RRA gene, or that APHIS's proposed interim measures would be insufficient to prevent any such harm in the future. The interim measures proposed by APHIS would have satisfied its obligation under NEPA to refrain from activities that would have an adverse environmental impact or would limit the choice of reasonable alternatives pending completion of an EIS. The district court ignored traditional principles governing review of administrative action in refusing to defer to the interim measures APHIS proposed based on its scientific exper-

tise. The court substituted its own judgment about the measures needed to prevent gene flow from RRA fields to non-RRA alfalfa fields while APHIS prepares the EIS.

This Court need not decide whether the district court was required to hold an evidentiary hearing including live witness testimony prior to entering the permanent injunction because the existing record makes clear that the injunction is overly broad. The error committed by the district court was not a failure to obtain necessary evidence, but a failure to apply the correct legal standard to the facts in the existing record, which show that the possibility of gene flow is *de minimis*. If the Court reaches the issue, however, it should not adopt a rule that invariably requires a district court to hear live testimony in an Administrative Procedure Act (APA) case before deciding whether to enter permanent injunctive relief. Although a district court may need to receive additional evidence to assess the appropriateness of equitable relief, the court should be permitted to exercise its discretion in deciding how to do so, including through written submissions.

ARGUMENT

The district court held that APHIS violated NEPA by preparing an EA instead of an EIS in conjunction with petitioner's request to have RRA deregulated, and the court ordered APHIS to prepare an EIS. Neither APHIS nor petitioners appealed those rulings. But this Court has made clear that the finding of a statutory violation by a government agency does not necessarily justify the entry of an injunction barring the proposed action. *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 311, 313 (1982). On the contrary, the entry of an injunction

may be awarded only upon a separate showing that the plaintiff is entitled to such relief. *Winter* v. *NRDC*, 129 S. Ct. 365, 375-376 (2008).

Moreover, even when injunctive relief is found appropriate, that relief must be tailored to address the statutory violation, taking into account the respective harms to the parties, measures that can be taken to mitigate those harms, and the public interest. See, *e.g.*, *Winter*, 129 S. Ct. at 376-381. The essence of a court's equity jurisdiction is the power to mold each injunction "to the necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312; see also *Lewis* v. *Casey*, 518 U.S. 343, 359-360 (1996) (citing cases); *Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979).

The federal parties do not challenge the propriety of some injunctive relief in this case to cure the violation of NEPA found by the district court and to minimize the prospect of environmental harm while APHIS prepares an EIS. The courts below erred, however, in rejecting APHIS's proposed interim measures, which were carefully tailored to accomplish those purposes, and instead imposing a broad injunction barring all future sales and planting of RRA.

The district court in this case applied the wrong legal standard, effectively presuming that the NEPA violation caused irreparable injury and justified the entry of a broad injunction. And the court of appeals erred in upholding that injunction, which is not tailored to the circumstances of the case and cannot be supported by a proper balancing of equities.

I. THE DISTRICT COURT APPLIED THE WRONG STANDARD IN ISSUING THE PERMANENT INJUNCTION

This Court has frequently articulated the standard a plaintiff must meet to justify a district court's entry of a permanent injunction. As this Court reiterated in *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006):

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

See also *Romero-Barcelo*, 456 U.S. at 312 ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies."); *Winter*, 129 U.S. at 374, 381.

Contrary to this clear mandate, the district court enjoined—first preliminarily and then permanently—all commercial planting of RRA, without requiring respondents to demonstrate that they had suffered or likely would suffer irreparable harm in the absence of such an injunction, that remedies at law would be inadequate to compensate them for any injury, and that the balance of harms warranted more than the measures submitted by APHIS. Pet. App. 54a-59a, 60a-79a. Although the court of appeals recited the appropriate legal standard, see *id.*

at 11a, its determination that the district court correctly applied that standard cannot be squared with the course of proceedings in this case.

A. The District Court Entered The Permanent Injunction Based On An Erroneous Presumption That An Injunction Should Be Entered Except In Unusual Circumstances

1. Under traditional principles of equity, "the scope of injunctive relief is dictated by the extent of the violation established." *Yamasaki*, 442 U.S. at 702. In this case, the district court found a single statutory violation: APHIS's failure to prepare an EIS under NEPA before deregulating RRA. Specifically, the court concluded that APHIS did not adequately study the potential for gene flow from RRA to conventional and organic alfalfa and the potential for the development of glyphosate-resistant weeds. Pet. App. 35a-47a. APHIS did not appeal the portion of the permanent injunction that ordered "the government to prepare an EIS before it makes a decision on Monsanto's deregulation." *Id.* at 79a. But in ordering a halt to all commercial planting of RRA pending completion of the EIS, rather than approving APHIS's proposed conditions on planting, the district court incorrectly exercised its equitable jurisdiction.

NEPA imposes procedural requirements on federal agencies, but does not require an agency to choose any particular substantive result. *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989). An agency's failure to conduct the "hard look" required by NEPA before undertaking a particular action, see *Winter*, 129 S. Ct. at 376 (quoting *Methow Valley Citizens Council*, 490 U.S. at 352), does not, in itself, constitute

irreparable injury to the plaintiff. *Summers* v. *Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009). As in any case seeking to enjoin government action, an injunction in a NEPA case must be based, *inter alia*, on a finding that the action at issue has caused or is likely to cause irreparable injury to the plaintiff.

As a matter of practical experience, cases involving claims of significant harm to the environment may result in injunctive relief more often than private litigation involving economic or other interests. As this Court observed in *Amoco Production Co.* v. *Village of Gambell*, 480 U.S. 531 (1987), certain types of injury cannot be undone. "Environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable. If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment." 480 U.S. at 545.

But the Court in *Amoco Production Co.* explicitly rejected a standard under which, in the absence of "unusual circumstances," "[i]rreparable damage is presumed when an agency fails to evaluate thoroughly the environmental impact of a proposed action." 480 U.S. at 541, 544-545 (quoting *People of the Vill. of Gambell* v. *Hodel*, 774 F.2d 1414, 1423 (9th Cir. 1985), rev'd in part and vacated in part, 480 U.S. 531 (1987)). Such a "presumption," the Court held, "is contrary to traditional equitable principles." *Id.* at 544-545. Rather, in every NEPA case (as in every other kind of case), a plaintiff must demonstrate that it has suffered or is likely to suffer irreparable injury to obtain an injunction. Not every NEPA plaintiff will be able to make that showing, and respondents did not do so here.

Ignoring *Amoco*, the district court in this case relied on Ninth Circuit cases holding that, "in the run of the mill NEPA case," an injunction should issue delaying the agency action in question, and that such an injunction should be denied only in "unusual circumstances." Pet. App. 65a-66a (quoting *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002), and citing *National Parks & Conservation Ass'n* v. *Babbitt*, 241 F.3d 722, 737 (9th Cir. 2001), cert. denied, 534 U.S. 1104 (2002)); see also *id.* at 55a. Although the courts below gave lip service to the proposition that an injunction does not automatically issue upon the finding of a NEPA violation (see *id.* at 65a; *id.* at 11a), they effectively flouted the bedrock principle of equity that an injunction must be based on a likelihood of irreparable harm.

APHIS's decision to deregulate RRA without the appropriate EIS does not itself establish or create a presumption of irreparable harm to respondents or the environment. In *Romero-Barcelo*, this Court explained that, "[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." 456 U.S. at 313 (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)). NEPA does not restrict the equity jurisdiction of federal courts, either explicitly or implicitly, and "nowhere specifies the consequences of a failure" by agency officials to prepare an EIS. See *Brock* v. *Pierce County*, 476 U.S. 253, 259 (1986). Neither do the applicable NEPA regulations require cessation of all agency actions or activities during the course of the NEPA process. See 40 C.F.R. 1506.1(a); see also *National Audubon Soc'y* v. *Department of the Navy*, 422 F.3d 174, 203 (4th Cir. 2005) ("The CEQ regulations and our own

caselaw make clear that agency action prior to completing a sufficient environmental study violates NEPA only when it actually damages the environment or 'limit[s] the choice of reasonable alternatives.'") (citation omitted). The district court's determination in this APA suit that APHIS had violated NEPA's procedural requirements therefore was not itself sufficient to support the district court's broad injunction.[1]

The district court purported to find the necessary irreparable injury in respondents' assertion that they faced a risk of "contamination of organic and conventional alfalfa crops with the genetically engineered gene" in RRA. Pet. App. 71a. As an initial matter, a plaintiff must demonstrate more than a mere possibility of irreparable harm in order to be entitled to injunctive relief. In the context of a preliminary injunction, this Court made clear in *Winter* that a plaintiff must "demonstrate that irreparable injury is *likely* in the absence of an injunction." 129 S. Ct. at 375. The same considerations apply in determining whether a permanent injunction is appropriate. See *id.* at 381. Indeed, this Court stated in *eBay* that a plaintiff must demonstrate

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[1] In authorizing review of agency action in a suit for declaratory or injunctive relief, see 5 U.S.C. 703, the APA suggests no departure from the well-established rule that the party seeking an injunction bears the burden of establishing that such relief is necessary. See, *e.g.*, *eBay*, 547 U.S. at 391. Indeed, the APA's very authorization of "declaratory judgments," 5 U.S.C. 703, indicates that the APA does not compel an injunction when agency action is found unlawful. See H.R. Rep. No. 1980, 79th Cong., 2d Sess. 42 (1946) (referring to possibility of suits for declaratory relief to "determine the validity or application of a rule or order"); see also S. Rep. No. 752, 79th Cong., 1st Sess. 26 (1945). Thus, under the APA, a party challenging agency action must demonstrate that a declaratory judgment would be inadequate and that the further relief of an injunction is necessary.

"that it *has suffered* an irreparable injury," 547 U.S. at 391 (emphasis added), to qualify for a permanent injunction, a standard that cannot be satisfied by unsupported assertion of a potential future harm. There was no showing that RRA had significantly affected conventional or organic alfalfa crops, or that any such effect was imminent or likely. That omission properly required the district court to adopt APHIS's proposed safeguards and reject respondents' request for nationwide injunctive relief barring all sales and commercial planting of RRA until an EIS is completed.[2]

In sum, the district court predicated the injunction it imposed on the NEPA violation alone, effectively pre-

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[2] In support of their motion for permanent injunctive relief, respondents submitted declarations of growers of non-genetically engineered alfalfa expressing their fears that their crops would be affected by RRA and that they accordingly would suffer economic loss. See, *e.g.*, J.A. 380, Geertson Decl. ¶ 6 (stating that allowing the planting of RRA is "threatening" to non-RRA crops); J.A. 400-401, Asumendi Decl. ¶¶ 3-6 (relating company's fear that it will be unable to choose to grow conventional alfalfa, and will lose money); J.A. 404, Holtz Decl. ¶ 5 (stating that he is "very concerned" about the release of RRA); J.A. 409, Gauntt Decl. ¶ 5 (concerned that widespread planting of RRA will threaten overseas business); J.A. 666, Baxter Decl. ¶ 6 ("While I have not been contaminated yet, I believe it is only a matter of time."). However, respondents did not claim that any of them had actually experienced such an impact or consequent economic loss. One declarant claimed to have abandoned his organic alfalfa operation because of a fear of liability if his seed acquired the RRA gene and affected another farmer's organic seed, but did not state that such an effect had actually occurred. J.A. 398-399, Schmaltz Decl. ¶¶ 10-11. Similarly, other declarants claimed to have heard second-hand reports of RRA gene flow. J.A. 663-664, Nichols Decl. ¶¶ 6-8; J.A. 1008-1009, Briggs Decl. ¶¶ 13-15. Respondents also speculated, based on a pollen flow study that had documented the RRA gene in feral alfalfa located 1.7 miles from an RRA seed field, that some gene flow could occur. E.R. 441, Pl. Mot. 8 n.4; J.A. 380-381, Geertson Decl. ¶¶ 8-10.

suming the existence of irreparable injury (and other prerequisites to an injunction) in the absence of "unusual circumstances," rather than actually finding harm. Pet. App. 65a-66a. In entering its injunction, the district court stated that it had already found in its initial memorandum and order finding the NEPA violation that cross-pollination had occurred. See *Id.* at 71a. But the district court's reliance on its earlier order exposes its error, because the discussion there addressed only whether APHIS had adequately considered the potential for infiltration of conventional alfalfa crops by RRA, not whether such infiltration had actually occurred. *Id.* at 35a-45a.[3] Without a finding that harm from such infiltration had occurred or is likely to occur, the district court's injunction cannot stand.[4]

2. Even if respondents had demonstrated a significant risk that RRA would enter some fields of conventional and organic alfalfa crops through cross-pollination, that showing would not have supported the broad

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[3] Although the district court purported to find that some cross-pollination had already occurred, it relied on hearsay evidence submitted by respondents, none of which in fact showed that a meaningful level of cross-pollination had occurred under conditions similar to those proposed by APHIS. Pet. App. 404a-407a. One alleged incident involved the discovery of the RR gene in a non-RRA seed lot. *Id.* at 404a. But petitioners demonstrated that any intermingling of RRA in that grower's seeds was likely caused by the grower's own use of RRA or was a false positive due to lab contamination. *Id.* at 405a.

[4] The district court elsewhere appeared to acknowledge that it had not adequately assessed the risk that adverse effects would result if RRA cross-pollinated some conventional or organic alfalfa fields. Indeed, the court declined even to engage in that analysis because doing so would, in the district court's view, "require th[e] Court to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." Pet. App. 68a.

permanent injunction the district court entered. Respondents did not show—and the district court did not find—that such an effect would cause irreparable harm.

a. As an initial matter, there is no evidence in the record that gene flow from RRA would destroy other types of alfalfa, even if left completely unchecked rather than subjected to the safeguards embodied in the APHIS conditions. The glyphosate-resistant gene in RRA is not contagious; it will not transform a non-RRA alfalfa plant into RRA upon mere contact. See Pet. App. 232a, 386a; J.A. 355. If RRA plants were to cross-pollinate with conventional or organic alfalfa, the pollinated non-RRA plant might produce seeds with the RRA gene. But the original non-RRA plant would not be transformed into an RRA plant. And the likelihood that such an RRA-affected seed would be produced—and then would grow into a mature RRA plant—is small and dependent on the occurrence of a series of unlikely events.

First, an RRA field must be permitted to flower and, therefore, produce pollen. J.A. 438; Pet. App. 230a. Farmers who grow RRA for hay and forage—as 99% of alfalfa farmers do, Pet. App. 321a—do not generally permit their fields to flower in any significant degree because flowering decreases the nutritional value of the plant, which also reduces its economic value. Pet. App. 128a, 279a; J.A. 346-347, 355, 483-484, 565.

Second, assuming a field flowers more than the grower intended (because, for example, of weather-related delays in mowing, see Pet. App. 70a), pollinating bees must transfer the pollen from those flowers to another field. J.A. 438; Pet. App. 230a. In fields grown for hay and forage, farmers do not stock their crops with pollinators because they do not intend to permit the

plants to flower. J.A. 438; Pet. App. 230a-231a, 279a. Thus, pollination could occur only through feral bees; but feral bees are unlikely to be attracted to RRA fields grown for hay or forage because such fields generally produce few flowers. J.A. 356; Pet. App. 128a-130a, 231a.

Third, a pollinator would have to travel to a non-RRA alfalfa field that was flowering simultaneously—an unlikely event given that different varieties of alfalfa flower at different times—and to pollinate one or more of those flowers. J.A. 438.

Fourth, the grower of the non-RRA alfalfa would have to allow his crop to produce seeds, which generally occurs at least a month after the crop flowers. Only if plants in the non-RRA crop that have been fertilized with pollen from an RRA plant produce seeds might an RRA plant grow in a non-RRA alfalfa field. J.A. 438; Pet. App. 231a. But the grower with a non-RRA hay field is unlikely to postpone cutting for that long, because, as explained above, the alfalfa would lose nutritional and economic value.

Finally, the seed would have to actually grow into an RRA plant. But that is unlikely if the seed simply drops to the ground in that field because alfalfa exhibits autotoxicity, meaning that alfalfa seeds do not germinate well in established alfalfa fields. J.A. 347, 438; Pet. App. 232a-233a.[5]

Given this necessary chain of improbable events, the chance that RRA would infiltrate and germinate in any alfalfa field grown for hay or forage is exceedingly low. And the interim safeguards APHIS submitted to the

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[5] In addition, alfalfa seeds are relatively heavy and therefore unlikely to be carried by the wind outside of that field. Pet. App. 130a. Nor does alfalfa shed pollen to the wind. *Id.* at 230a.

district court would further protect against that possibility.

b. Even if some RRA were to take root in a conventional alfalfa hay or seed field, the economic harm to the grower of the affected crop is compensable with money damages. That harm, as an initial matter, is not likely to be significant. The grower might lose some potential buyers, but could continue to sell the affected alfalfa in markets not sensitive to the presence of genetically modified plants.[6] And if the grower preferred to rid its field of the crop containing some RRA plants, it could do so by using common techniques of clearing the field and then replanting with non-RRA alfalfa seed within one

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[6] Indeed, the infiltration of RRA into a conventional alfalfa field would not necessarily cause an organic grower to lose its USDA organic certifications. The USDA National Organic Program (NOP) was established in 1990 to create uniform standards governing the marketing of organic crops. See Organic Foods Production Act of 1990, 7 U.S.C. 6501 *et seq.* The process-based NOP "requires organic production operations to have distinct, defined boundaries and buffer zones to prevent unintended contact with prohibited substances, such as modified genes, from adjoining land that is not under organic management." Pet. App. 37a (citation omitted). But the NOP regulations do not prohibit the sale of a crop as organic merely because it has been affected by genetic drift from a crop that has been genetically engineered. 65 Fed. Reg. 80,556 (2000) ("The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation."). Indeed, the issue of genetic drift was raised during the rulemaking process for the NOP, and USDA rejected suggestions that restrictions should be placed on the growers of genetically engineered crops to protect against genetic drift. See *ibid.* Instead, USDA explained that, "[a]s long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation." *Ibid.*

growing cycle. Pet. App. 387a, 397a, 409a-410a.[7] In any event, this economic harm is fully compensable by money damages from the responsible private party, assuming a court were to find that a legal injury had occurred. Because traditional legal remedies would suffice to cure economic harm from gene flow, that harm cannot support the permanent injunction. *E.g.*, *Romero-Barcelo*, 456 U.S. at 312.

c. The case would be different if the district court had found irreparable harm to a plant species, but no evidence of such harm exists. It is a great leap from a finding of cross-pollination (assuming that were justified) to a finding of significant harm to any species of conventional alfalfa. With respect to animal species, the "loss of only one [animal] is [not a] sufficient injury to warrant a preliminary injunction"; a plaintiff "must demonstrate 'a substantial likelihood of * * * irreparable harm'" to his own interests resulting from some form of "irretrievabl[e] damage [to] the species." *Fund for Animals* v. *Frizzell*, 530 F.2d 982, 986-987 (D.C. Cir. 1975) (citation omitted); accord *Water Keeper Alliance* v. *United States DoD*, 271 F.3d 21, 34 (1st Cir. 2001) (death of a "single member of an endangered species" does not qualify as irreparable harm absent showing of how "probable deaths * * * may impact the species"). The same analysis should apply for a plant species. An adverse effect on plants in one or several fields of a crop as widely grown as alfalfa is not irreparable injury to the species. Hence, this case differs markedly from NEPA cases in which irreparable environmental harm

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[7] In addition, a grower of non-RRA alfalfa can engage in self-help to prevent the possibility of RRA's infiltrating his field by mowing it before the crop produces seeds—a practice that is in his economic interest in any case. See p. 36, *supra*.

will result from the statutory violation. Here, at most economic harm, and not any irreparable harm to a species, is a plausible consequence of declining to enter an injunction.

3. Finally, the district court erred in balancing the equities in this case. RRA was commercially available for nearly two years during the pendency of the merits phase of the litigation, during which time respondents did not seek a preliminary injunction. In that period, more than 3000 growers in 48 states planted approximately 220,000 acres of RRA, in reliance on APHIS's deregulation decision. See J.A. 350. While the permanent injunction does not require the destruction of any RRA for which seed was purchased before March 12, 2007, and which was planted before March 30, 2007, it removes RRA as a future option for both growers and consumers. The injunction also prevents petitioners from continuing to market their product. The district court dismissed that harm as the mere "loss of anticipated revenue"—without acknowledging that that is the same type of harm respondents would suffer if cross-pollination were to occur in their fields. Pet. App. 71a-72a. The district court did not explain why potential economic harm to the farmers represented by respondents outweighed acknowledged and substantial economic harm to Monsanto and FGI, as well as harm to growers and consumers who prefer RRA.

B. The District Court's Injunction Was Not Tailored To Cure The NEPA Violation

The district court erred in entering its permanent injunction for an additional reason: the injunction was not appropriately tailored to curing the NEPA violation. The goal of injunctive relief is to arrive at a "'nice ad-

justment and reconciliation' between the [parties'] competing claims" of injury resulting from "the granting or withholding of the injunction," by "balanc[ing] the conveniences of the parties and possible injuries to them" and "mould[ing] each decree to the necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312 (citations omitted). The district court's broad injunction failed to meet that standard.

1. As a general matter, the exercise of equitable discretion should be informed by the purposes and policies of the statute to be enforced. See, *e.g.*, *Hecht Co.* v. *Bowles*, 321 U.S. 321, 331 (1944) (equity jurisdiction must be exercised in light of the objectives of the relevant statute); *United States* v. *Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496-498 & n.9 (2001). If the relevant statute does not mandate an immediate prohibitory injunction for every violation, courts have the discretion to fashion more tailored relief to secure prompt compliance with the statute while taking account of other factors in the equitable calculus. In *Romero-Barcelo*, for example, the Court held that, instead of enjoining the challenged activity because of a violation of the Clean Water Act, a court could "order that relief it considers necessary to secure prompt compliance with the Act" by directing the agency to apply for a permit for the activity at issue. 456 U.S. at 320. The Court took a similar approach in *Amoco Production Co.*, see 480 U.S. at 541-546, noting that the district court's decision not to enjoin all oil exploration activities until the Interior Department completed a study of potential impacts on subsistence uses under the relevant statute "did not undermine" the policy of that statute. *Id.* at 544-546; see *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 498 n.9.

A similar approach is warranted in appropriate circumstances under NEPA. The failure to prepare an EIS does not necessarily require an injunction forbidding all action that would be addressed by the EIS while the agency undertakes its preparation. In a similar situation in *Winter*, for example, the Court noted that "[a] court concluding that the Navy is required to prepare an EIS has many remedial tools at its disposal, including declaratory relief or an injunction tailored to the preparation of an EIS rather than the Navy's training in the interim." 129 S. Ct. at 381.

As the Court has noted, the purpose of NEPA is to "ensure[] that [a federal] agency will not act on incomplete information, only to regret its decision after it is too late to correct." *Marsh* v. *Oregon Natural Res. Council*, 490 U.S. 360, 371 (1989); see *Winter*, 129 S. Ct. at 376; *Methow Valley Citizens Council*, 490 U.S. at 349; *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 558 (1978). That purpose is reflected in the CEQ regulations implementing NEPA, which impose limits on agency action pending completion of the NEPA process. Specifically, during the preparation of an EIS, an agency may not take any action in connection with the implicated activity that would "[h]ave an adverse environmental impact" or would "[l]imit the choice of reasonable alternatives." 40 C.F.R. 1506.1(a).

Consistent with these regulations, a court should not enter a broad injunction if an agency can show that the actions it will take pending preparation of an EIS will not materially harm the environment and will leave open a reasonable range of alternatives for final agency decision. And in determining whether the agency has satisfied this standard, the court should take into account whether there is "little if any information about pro-

spective environmental harms" in the case, or whether, even though an EIS has not yet been prepared, there already is a body of data and experience relating to the environmental and other consequences of the governmental action. *Winter*, 129 S. Ct. at 376.

2. a. In this case, the district court found that APHIS erred in deregulating RRA without preparing an EIS on the effects of RRA's cross-pollination (if any) of conventional and organic alfalfa. But the court's injunction was not properly tailored to curing that NEPA violation. The district court appropriately ordered APHIS to prepare an EIS regarding the deregulation. The contested question relates to the standards that should govern RRA while APHIS is preparing the EIS. In addressing that question, the district court was not limited either to allowing the deregulation to proceed (notwithstanding the NEPA violation), or to prohibiting all sale or commercial planting of RRA until the EIS is complete. The court instead should have adopted the agency's proposal for reasonable interim measures.

The determination of what interim measures should govern in such a case is appropriately based on scientific expertise informed by APHIS's considered judgment and experience in administering the PPA. APHIS is the agency charged by Congress with developing the relevant expertise and exercising the relevant judgment under the PPA—and also with implementing NEPA in connection with those responsibilities. APHIS accordingly submitted proposed interim measures to the district court. As explained below, the measures APHIS proposed were carefully tailored to address the statutory violation, prevent environmental injury, and address the other relevant equitable considerations during that interim period. Those measures also left open the

full range of reasonable alternatives available to APHIS at the completion of its EIS. The agency thus demonstrated the appropriateness of a tailored remedy.

b. Based on its extensive expertise with RRA and other genetically engineered plants, APHIS proposed that the district court include in its injunctive order six science-based conditions on RRA introduced between the date of the court's judgment and the completion of the EIS. Those proposed conditions specified: (1) isolation distances between RRA fields and conventional alfalfa seed production fields to mitigate potential cross-pollination;[8] (2) harvesting requirements to minimize potential cross-pollination; (3) cleaning requirements for farm equipment used in RRA production; (4) handling and identification requirements to minimize commingling of RRA and conventional or organic alfalfa after harvest; (5) a ban on RRA for livestock grazing purposes or in mixed-grass pastures; and (6) a requirement that all RRA seed producers and hay growers enter into contracts with petitioners promising compliance with these conditions. Pet. App. 185a-187a; see J.A. 439-445. APHIS explained the details and scientific basis for each of the proposed conditions in two declarations of the Director of the Environmental Risk Analysis Division for APHIS's Biotechnology Regulatory Services

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[8] The proposed measures would have required that RRA crops grown for hay be located at least 165 feet from any alfalfa field used for certified seed production. Pet. App. 186a. For RRA crops grown for seed production, the proposed measures would have required isolation distances of at least 1500 feet when leafcutter bees are used to pollinate the field and three miles when honey bees are used as pollinators. *Ibid.*

(BRS).[9] See J.A. 345-365 (Decl. of Neil Hoffman); J.A. 436-542 (Second Decl. of Neil Hoffman and exhibits).[10]

Those declarations explain that the potential for gene flow between RRA fields and conventional or organic alfalfa fields used for hay or forage is negligible. J.A. 438; J.A. 355-358. The Director based that expert judgment on scientific evidence that (1) there is no potential for gene flow in fields that do not produce seeds, even when pollen is present, J.A. 355; (2) gene flow cannot occur unless flowering in proximate fields is simultaneous, which is unlikely given the number of alfalfa varieties that are grown, J.A. 355, 438; (3) gene flow requires the presence of sufficient pollinators as well as significant movement by pollinators among fields, which is unlikely because growers do not stock alfalfa fields grown for hay or forage with pollinating bees, *ibid.*; and (4) successful gene flow would require fertile embryos to mature, fall to the ground, and germinate in spite of the effects of autotoxicity and competition from mature plants, *ibid.*; see pp. 25-27, *supra*. The Director also explained the scientific basis for his proposed isolation distance requirement. J.A. 439-441.[11]

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[9] BRS is the division of APHIS that is responsible for regulation of the importation, interstate movement, and release into the environment of genetically engineered plants. J.A. 345.

[10] The Director based his conclusions on various scientific studies of the potential for gene flow from RRA to other types of alfalfa. Those sources, which were submitted to the district court, are included at J.A. 446-542.

[11] The Director relied on scientific evidence that: (1) an isolation distance of 165 feet between an RRA hay field at 20%-50% bloom (a considerably higher level of bloom than APHIS's proposed interim measures would have permitted) and a seed field was found to reduce pollen-mitigated gene flow to under 0.2% for leaf cutter bees and 0.3% for honey bees; and (2) isolation distances of 1500 feet for leaf cutter

c. It is well established that courts should defer to the conclusions of agency officials that are based on expertise and scientific evidence. *E.g.*, *Oregon Natural Res. Council*, 490 U.S. at 376-377; *BG&E*, 462 U.S. at 103. That deference is due even when an agency has initially failed to comply with procedural requirements established by statute. See *Brock* v. *Pierce County*, 476 U.S. 253, 260 (1986) (the Court "would be most reluctant to conclude that every failure of an agency to observe a procedural requirement voids subsequent agency action, especially when important public rights are at stake"); *Barnhart* v. *Peabody Coal Co.*, 537 U.S. 149, 157-163 (2003). The district court here concluded that APHIS erred in failing to prepare an EIS regarding deregulation of RRA. Pet. App. 33a-47a. But that determination did not excuse the court from according appropriate deference to the agency's subsequent determination, based on scientific and regulatory judgment and expertise, of the interim measures appropriate pending the EIS's completion.

This Court has held:

> If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being re-

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bees and three miles for honey bees between RRA grown for seed production and other alfalfa fields used for seed production were found to reduce pollen-mediated gene flow to under 0.1%. J.A. 439-440.

viewed and to reach its own conclusions based on such an inquiry.

Florida Power & Light Co. v. *Lorion*, 470 U.S. 729, 744 (1985); see *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973). Under these principles, if a court orders a remand after finding that an administrative agency has failed to support its decision not to prepare an EIS, the agency typically will have substantial discretion about how best to respond to the court's order. As an initial matter, the agency can choose whether to develop a more complete EA and explanation, to prepare an EIS, or to abandon the proposed action altogether. See, *e.g.*, *Center for Biological Diversity* v. *National Highway Traffic Safety Admin.*, 538 F.3d 1172, 1226-1227 (9th Cir. 2008); *O'Reilly* v. *United States Army Corps of Eng'rs*, 477 F.3d 225, 239-240 (5th Cir. 2007); *San Luis Obispo Mothers for Peace* v. *NRC*, 449 F.3d 1016, 1035 (9th Cir. 2006), cert. denied, 549 U.S. 1166 (2007). And if the agency decides to prepare an EIS, it can determine the appropriate way to meet environmental concerns, including the adoption of interim measures mitigating environmental impact, while preparation of the EIS is ongoing. Cf. *Motor Vehicles Mfrs. Ass'n of the United States, Inc.* v. *State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 57 & n.21 (1983).

In this case, APHIS did not request that the court remand to allow it to consider that full range of options. But that difference should not so dramatically affect the outcome as it did in this case. Here, the Director of APHIS's BRS expressed his expert judgment in a submission filed with the court, rather than in an administrative proceeding following a formal remand. In that submission, he proposed conditions that the PPA would have allowed APHIS to adopt on remand as interim

measures. Just as a court would have deferred to the agency's decision on an administrative remand, so too the district court should have deferred to the Director's submission. That submission was no less based on scientific and technical expertise in implementing the PPA, as well as on the agency's responsibility to take into account the requirements of NEPA. See, *e.g.*, 7 U.S.C. 7701(3) ("it is the responsibility of the Secretary to facilitate * * * interstate commerce in agricultural products * * * that pose a risk of harboring plant pests * * * in ways that will reduce, to the extent practicable, *as determined by the Secretary*, the risk of dissemination of plant pests") (emphasis added). Cf. *Bell* v. *Wolfish*, 441 U.S. 520, 547 (1979) (noting deference accorded remedies proposed by government officials in institutional reform litigation); *Pell* v. *Procunier*, 417 U.S. 817, 827 (1974) (same).

The district court therefore erred in rejecting APHIS's proposed interim measures and instead prohibiting all planting of RRA. APHIS adequately explained, by reference to scientific evidence, the basis for its proposed measures, which would have subjected RRA to significant regulation pending completion of an EIS. The proper role of the district court in reviewing the agency submission was not to determine whether it would have reached the same conclusion about the risk and consequences of cross-pollination. *Oregon Natural Res. Council*, 490 U.S. at 378, 385. Respect for APHIS's "substantial agency expertise," *id.* at 376, in assessing the effect of plant products on the environment called for deference by the court to "the reasonable opinions of [APHIS's] own qualified experts even if, as an original matter, [the] court might [have found] contrary views more persuasive." *Id.* at 378. In declining to adopt

APHIS's proposed interim measures pending completion of an EIS, and instead imposing its own broad prohibitory injunction, the district court failed to respect the domain that Congress has set aside for the administrative agency, *SEC* v. *Chenery Corp.*, 332 U.S. 194, 196 (1947), and "exercise[d] an essentially administrative function," *FPC* v. *Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 334 (1976) (*Transcontinental Gas*) (quoting *FPC* v. *Idaho Power Co.*, 344 U.S. 17, 21 (1952)).

II. THE DISTRICT COURT WAS NOT REQUIRED TO HOLD A FULL EVIDENTIARY HEARING WITH LIVE-WITNESS TESTIMONY AND CROSS-EXAMINATION ON THE SCOPE OF INJUNCTIVE RELIEF

1. Petitioners urged this Court to grant certiorari in part because the district court presumed irreparable harm without holding a hearing that included live-witness testimony and cross-examination. See Pet. 18-28. There is no need for this Court to address the hearing issue. The error committed by the district court, and condoned by the court of appeals, was not the failure to receive additional evidence in a different format. As discussed above, the district court erred in presuming that irreparable injury would result from APHIS's action unaccompanied by an EIS, and compounded that error in refusing to accord the requisite deference to APHIS's judgment concerning the appropriate interim measures pending completion of an EIS. Those errors, either alone or in combination, are sufficient to warrant vacating the injunction the district court entered and replacing it with APHIS's proposed interim measures without any need to consider the hearing issue. Indeed, in the court of appeals, petitioners agreed with APHIS

that the district court could have adopted APHIS's proposed interim measures in an injunctive order without first holding an evidentiary hearing. See Monsanto C.A. Br. 47-48.

2. If the Court should nonetheless decide to consider the hearing issue, it should hold that the district court did not err in declining to conduct a trial-type hearing in the circumstances of this case. A federal court plays a different role in an equitable suit challenging agency action under the APA than in a suit between private parties, and accordingly may take a different approach to addressing such factual issues.

If a district court needs to consider evidence beyond the administrative record in determining whether to enter an injunction in an APA case, the court may ordinarily do so through means other than a live evidentiary hearing. Petitioners are correct that, as a general matter, a litigant is entitled to have material factual disputes resolved by a district court based on evidence from the parties. But it does not follow that a district court is required to receive that evidence in a trial-type proceeding in an equitable action for review of agency action under the APA.

The court in such a case instead may consider the parties' competing views by holding a "paper hearing" involving the review of written submissions. That is what happened, for example, in the preliminary injunction proceedings in *Winter*. In that case, the Navy adopted certain interim measures to protect the environment while it prepared an EIS and the district court imposed several more; based on its consideration of declarations, the EA, and other material that the parties submitted, this Court then determined whether the scope of the injunctive relief entered was appropriate

based on that record. See 129 S. Ct. at 371-373, 376-378. Similarly, in *United States* v. *B&O R.R.*, 225 U.S. 306, 323 (1912), this Court held that the Commerce Court, in considering whether to grant a preliminary injunction against enforcement of an order of the Interstate Commerce Commission, should apply "general principles of equity" to determine the propriety of issuing such an injunction "on the face of the papers presented."[12]

The permissibility of that approach follows from the nature of the administrative process that precedes judicial review under the APA. The APA provides for an agency hearing with presentation of live testimony in rulemaking or adjudicatory proceedings only when required by another statute. See 5 U.S.C. 553, 554, 556(a). A trial-like evidentiary hearing "is neither a required, nor even the most effective, method of decisionmaking in all circumstances." *Mathews* v. *Eldridge*, 424 U.S. 319, 348 (1976). Even in the context of individualized determinations, factual disputes may be resolved on written submissions—*i.e.*, without an oral hearing—when their resolution is unlikely to involve credibility determinations. *Yamasaki*, 442 U.S. at 696. And an agency may freely exclude from individual evidentiary hearings, and instead resolve in a more general proceeding, any predictive or legislative-type issues affecting

[12] The Hobbs Judicial Review Act, 28 U.S.C. 2341 *et seq.*, now vests jurisdiction in the courts of appeals to review certain administrative actions, and grants the courts authority to enjoin enforcement of such orders pending review based on "evidence submitted to the court of appeals." 28 U.S.C. 2349(b). There is no requirement for an evidentiary hearing. In immigration cases, which are subject to judicial review under the Hobbs Judicial Review Act, see 8 U.S.C. 1252(a)(1), courts of appeals routinely dispose of requests for stays in immigration cases based on written submissions, without holding an evidentiary hearing.

numerous persons. See *Mobil Oil Exploration & Producing Se., Inc.* v. *United Distribution Cos.*, 498 U.S. 211, 228 (1991); *United States* v. *Florida E. Coast Ry.*, 410 U.S. 224, 239-240 (1973); see also Henry J. Friendly, *Some Kind of Hearing*, 123 U. Pa. L. Rev. 1267, 1302-1303, 1307 (1975) (*Some Kind of Hearing*). A trial-type administrative hearing may be especially unwarranted when an agency's decision is based on scientific or other expert evidence. *Mathews*, 424 U.S. at 344-346; *Some Kind of Hearing* 1284-1285 (noting that, in cases dealing with "recondite scientific or economic subjects[,] * * * the main effect of cross-examination is delay"). Determinations of this kind typically are legislative or regulatory in nature, rather than dependent on the adjudication of historical or personal facts.[13]

In administrative proceedings under the PPA, parties are not entitled to a trial-like hearing to air their views about whether a regulated article should be prohibited or deregulated in whole or in part.[14] Nothing in

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[13] Although some courts of appeals have found error in a district court's failure to hold an evidentiary hearing prior to entry of an injunction, those cases are predominantly non-APA cases or cases in which the court is called upon to resolve historical facts particular to the litigants before it. That was the case, for example, in *United States* v. *Microsoft Corp.*, 253 F.3d 34, 101-103 (D.C. Cir.), cert. denied, 534 U.S. 952 (2001), in which the court of appeals held that the district court should have held an evidentiary hearing on the propriety and scope of the remedy before ordering Microsoft to submit a plan for divestiture.

[14] Under APHIS regulations, when the agency receives a deregulation petition, it must publish in the *Federal Register* a notice of such petition and shall specify that any interested person may submit written comments regarding the petition to APHIS for a period of at least 60 days. 7 C.F.R. 340.6(d)(2). The regulations also provide that, if a petition for deregulation is denied, there is an opportunity for an appeal on the basis of written submissions, although the Administrator

the PPA or its implementing regulations requires such a hearing. Nor are parties entitled to such a hearing as part of APHIS's NEPA process. If petitioners would not have a right to a trial-type hearing on such issues before the agency—either in the first instance or if the court had remanded the case to APHIS—it is hard to see why they should gain that right by intervening in the part of an APA action regarding the same issues.[15] And nothing in the nature of those issues suggests the need for an individualized hearing. In the NEPA context, the propriety of equitable relief is likely to turn on legislative-type judgments involving scientific or economic data, rather than on adjudicative assessments of the credibility or accuracy of fact witnesses to historical events. Accordingly, a court considering such relief may do so by evaluating the agency's and other parties' written submissions.

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may, at his discretion, provide an informal hearing. See 7 C.F.R. 340.6(f).

[15] In addition, in-court evidentiary hearings that would require the testimony of agency officials responsible for administering a federal program impose significant costs on the government. *United States* v. *Morgan*, 313 U.S. 409, 422 (1941) (quoting *Morgan* v. *United States*, 304 U.S. 1, 18 (1938)) (noting that courts reviewing agency action should not "probe the mental processes" of the agency's decisionmaker).

CONCLUSION

The judgment of the court of appeals should be reversed, and the case should be remanded with instructions to vacate the permanent injunction entered by the district court.

Respectfully submitted.

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MARCH 2010

RESPONDENT'S BRIEF

(15)

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO COMPANY, ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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QUESTIONS PRESENTED

1. Whether petitioners lack standing because the injunction they are challenging on appeal causes them no injury independent of that caused by the trial court's unchallenged decision to vacate the federal agency's order deregulating Roundup Ready Alfalfa.

2. Whether, under all the facts and circumstances of this case, the district court abused its discretion in issuing the permanent injunction.

3. Whether, under all the facts and circumstances of this case, the district court abused its discretion in declining to hold a trial-type evidentiary hearing.

RULE 14.1(B) STATEMENT

The plaintiffs-appellees in the United States Court of Appeals for the Ninth Circuit, who are respondents here, are Geertson Seed Farms (now known as Geertson Farms, Inc.), Trask Family Seeds, the Center for Food Safety, Beyond Pesticides, the Cornucopia Institute, the Dakota Resource Council, the National Family Farm Coalition, the Sierra Club, and the Western Organization of Resource Councils.

The defendants-appellants in the Ninth Circuit were Mike Johanns (in his official capacity as Secretary of the U.S. Department of Agriculture), Steve Johnson (in his official capacity as Administrator of the U.S. Environmental Protection Agency), and Ron Dehaven (in his official capacity as Administrator of the Animal Plant Health and Inspection Service, U.S. Department of Agriculture).

The intervenors-defendants-appellants, who are petitioners here, were Monsanto Company, Forage Genetics International, LLC, Daniel Mederos, and Mark Watte. John Grover was an intervenor-defendant-appellant in the Ninth Circuit but is not a party to this appeal.

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rules 24.1 and 29.6, there is no change to the corporate disclosure statement previously filed by respondents.

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STATEMENT

A. Regulatory Background

Congress enacted the Plant Protection Act ("PPA"), 7 U.S.C. § 7701 *et seq.*, to detect, control, eradicate, and suppress plant pests and noxious weeds. *Id.* § 7701(1). The PPA provides that "no person shall import, enter, export, or move in interstate commerce any plant pest," and it delegates to the Secretary of Agriculture authority to issue regulations to prevent the introduction and dissemination of plant pests. *Id.* §§ 7702(16), 7711(a) . The Secretary has delegated this authority to the Animal and Plant Health Inspection Service ("APHIS"). 7 C.F.R. §§ 2.22(a), 2.80(a)(36).

APHIS regulations govern "organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests." 7 C.F.R. §§ 340.0(a)(2) n.1, 340.6. The agency retains strict control over these "regulated article[s]," prescribing how they may be "introduce[d]" into the environment and forbidding their "release" or "move[ment in] interstate [commerce]" absent explicit approval. *Id.* § 340.1.

A person may obtain such agency approval in several ways. First, if an applicant complies with performance standards intended to limit the risk of unintentional dissemination, it may secure permission to conduct field trials of the regulated article. *Id.* § 340.3(e). Second, after submitting more detailed information, the applicant may receive a permit. *Id.* §§ 340.3(e)(5), 340.4. Finally, a person may petition APHIS for a determination that an item does not present a plant pest risk and therefore should not be

regulated at all. 7 U.S.C. § 7711(c)(2); 7 C.F.R. § 340.6. Before deciding whether to approve a deregulation petition, APHIS must publish notice and solicit public comments. 7 C.F.R. § 340.6(d)(2)-(3).

If deregulation would constitute a "major [f]ederal action[] significantly affecting the quality of the human environment," the National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. § 4321 *et seq.*, requires APHIS to consider and document the potential environmental effects in an environmental impact statement ("EIS"). *Id.* § 4332(2)(C). The agency may forego an EIS only if it "determines – based on a shorter environmental assessment (EA) – that the proposed action will not have a significant impact on the environment." *Winter* v. *NRDC*, 129 S. Ct. 365, 372 (2008).

APHIS must comply with regulations promulgated by the Council on Environmental Quality ("CEQ"), the agency responsible for overseeing implementation of NEPA. 40 C.F.R. § 1515.2. Those regulations provide, in relevant part, that the EIS "shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made." *Id.* § 1502.2(g). Pending completion of an EIS, APHIS must refrain from taking any action that would harm the environment, preclude alternative courses of action, or otherwise diminish the practical significance of the EIS. *Id.* § 1506.1(a); see also *id.* §§ 1500.1(b), 1501.2, 1502.2(f), 1502.5.

B. The Petition To Deregulate RRA

This case concerns the efforts of petitioners, Monsanto Company and Forage Genetics International,

LLC ("FGI"), to secure the deregulation of Roundup Ready Alfalfa ("RRA"). By virtue of genetic modification, RRA can survive application of glyphosate, a powerful non-selective herbicide that kills or severely damages most plant species, including conventional alfalfa. Pet.App.28a.

In 2004, petitioners asked APHIS to grant RRA non-regulated status. Pet.App.5a. APHIS prepared, and solicited public comments on, a draft EA. More than 663 comments were received, including 520 that opposed the deregulation. Pet.App.6a; 69 Fed. Reg. 68,300 (Nov. 24, 2004). Alfalfa farmers, exporters, and others objected that APHIS had not adequately considered the environmental effects of deregulation. See, *e.g.*, JA 111-50. Commenters also objected that, without appropriate safeguards, RRA's genetically engineered trait would spread to conventional and organic alfalfa. *E.g.*, JA 111-49.[1] Further, they noted that widespread adoption of RRA would exacerbate the increase in herbicide use caused by the growing of other Roundup Ready crops (such as corn, rice, and soybeans). JA 114-43; see also JA 239-44. This, in turn, would accelerate the proliferation of glyphosate-tolerant weeds, thereby driving farmers in a vicious cycle to apply *even more* glyphosate or to employ

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[1] Growers explained that alfalfa contaminated with the RRA gene cannot be marketed and sold as "conventional" or "organic." Many foreign nations – including Japan, the largest importer of alfalfa hay, and Saudi Arabia, the largest alfalfa seed importer – generally do not accept genetically engineered crops. JA 123-24, 130, 149-50, 450-54, 623-24 Organic dairy farms, cattle operations, and horse breeders also objected to deregulation because of the effects of a diminished supply of organic alfalfa hay. *E.g.*, JA 122-26; see also JA 420-23, 449, 454, 638, 646-50, 987-89.

other, more toxic herbicides. JA 114-26, 131-43; see JA 239-44, 678-83, 707-19.

APHIS nevertheless concluded that deregulation of RRA would not have significant environmental effects. Pet.App.7a. In June 2005, without preparing an EIS, the agency unconditionally deregulated RRA. *Ibid.*; JA 151-231.

C. The District Court Proceedings

In early 2006, Geertson Seed Farms and Trask Family Farms, which are conventional alfalfa seed farms in Oregon and South Dakota, together with the Center for Food Safety and other environmental groups, initiated this litigation against the Administrator of APHIS and two other federal officials. See page ii, *supra*. Among other things, plaintiffs (respondents here) challenged APHIS's deregulation decision under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, alleging that the agency's failure to prepare an EIS violated NEPA.[2]

1. Summary judgment proceedings and the preliminary injunction

On cross motions for summary judgment, and after lengthy arguments conducted on January 19, 2007, JA 245-55 (excerpts), the district court granted partial summary judgment, holding that APHIS had violated NEPA by failing to prepare an EIS before deregulating RRA. Pet.App.27a-53a. The court determined that increased distribution of RRA likely

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[2] The federal defendants below are also respondents in this case and will be referred to as "the federal respondents." "Respondents" will refer to the plaintiffs below.

would cause genetic contamination of conventional and organic alfalfa, and it found that the agency had failed to evaluate the effects of such contamination. Pet.App.35a, 38a-45a. The district court also held that APHIS had failed to assess the environmental significance of the anticipated proliferation of glyphosate-tolerant weeds (from RRA alone and cumulatively, because of other genetically modified crops) – a side-effect of deregulation that APHIS did not dispute. Pet.App.45a-47a. The court requested proposed judgments from the parties; in response, APHIS submitted an order that would have (i) vacated the deregulation decision but simultaneously (ii) allowed dissemination of RRA subject to certain conditions. JA 376-78.

Monsanto and FGI then moved to intervene. See JA 39-40. In their intervention pleadings, they asserted that they would be injured by *either* a vacatur of APHIS's deregulation decision *or* an injunction prohibiting distribution of RRA. Mot. to Intervene filed by Monsanto (Dkt. 86, filed Mar. 2, 2007), at 13 ("[r]escission of the USDA deregulation decision * * * could effectively bar further sales or planting of" RRA); Mot. to Intervene filed by Forage Genetics, Inc. (Dkt. 88, filed Mar. 2, 2007), at 8. The district court granted intervention, JA 548, and scheduled an additional hearing to ensure that intervenors (petitioners here) could be heard on the scope of the remedy, JA 413-17. The court encouraged all parties to submit any evidence that might guide the decision on preliminary relief and offered to "listen to * * * anybody that you suggest that I should hear on the subject." JA 551; see also JA 413-18.

Following a lengthy hearing on March 8, 2007, the district court issued an order (i) vacating APHIS's deregulation decision, (ii) directing that RRA "is once again a regulated article," and (iii) entering a preliminary injunction that "maintains the status quo" by "prohibiting future plantings" pending the ruling on permanent injunctive relief. Pet.App.54a-59a, 63a; see also 72 Fed. Reg. 13,735-36 (Mar. 23, 2007). To allow growers who had already purchased RRA seed to plant it, the court postponed the effective date of that order by several weeks. Pet.App.58a. The court again encouraged the parties to submit "whatever additional evidence [they] wish to provide" prior to the hearing on permanent relief. Pet.App.58a-59a.

2. The permanent injunction proceedings

The parties thereafter filed scores of written declarations and other evidence. The "voluminous" (Pet.App.64a) record before the district court included extensive evidence of likely and irreparable environmental harm. We catalogue that evidence below.

a. *The preexisting contractual obligations.* Both before and after APHIS's June 2005 deregulation decision, the growth and harvesting of RRA was governed by petitioners' contracts with growers, which imposed mandatory isolation distances and required specific harvesting, cleaning, processing, labeling, and storage procedures. JA 610-15, 624-25; see generally JA 258-344. For example, the contracts required that RRA seed production fields be located certain minimum distances from existing conventional alfalfa seed fields, depending on whether pollen flow was mediated by leafcutter bees (900 feet), alkali bees (one mile), or honey bees (three miles). JA

263, 280-81, 615. For their part, growers of alfalfa hay were required to harvest their crop at or before 10 percent bloom. JA 260-61, 334, 624. And all growers of both seeds and hay were obligated to thoroughly clean tractors, combines, and other equipment used to harvest and process RRA products "both prior to and subsequent to" their use. JA 329; see also JA 271, 283-84, 287-88, 325, 349. All growers were also required to separate RRA seed from conventional seed and to store the former in specially marked containers. JA 268, 283-84, 329, 360.

b. *The evidence of past contamination in four states.* The evidence showed that, despite the foregoing contractual requirements, conventional alfalfa seed producers experienced contamination by RRA in at least four different states. In 2006, Dairyland Seed Company, a large family-owned farm, suffered contamination by the RRA gene in at least 11 of its conventional alfalfa seed lots. JA 1008-10, 1013-14, 1017-19, 1022-24; see also JA 630, 663-64, 666. The compromised lots were in Montana, Wyoming, and Idaho, where growers stock leafcutter bees to pollinate their seed fields, JA 358, and thus where RRA growers would have been contractually bound to 900-foot isolation distances. JA 263. The contamination of Dairyland's seeds occurred well beyond that distance; indeed, meaningful levels of contamination were detected at up to 1.5 miles from the RRA source. JA 1018.

Similarly, Cal/West, a California-based seed cooperative, experienced two contamination episodes in 2005. JA 670-75. First, the company discovered that, less than 200 feet away from one of its seed produc-

tion fields in Wyoming, a neighbor had planted a field of RRA. JA 673. Although Cal/West and the neighbor apparently had planted without knowledge of the other's actions, the unsafe proximity was not discovered until well after each field was established. When tested, the Cal/West field showed significant levels of RRA contamination. *Ibid.*

Cal/West also discovered the presence of the RRA gene in one of its conventional seed lots in California. JA 672. The company then tested seed produced in Washington from plants that were grown using the California-based seed. *Ibid.* Two of the sampled Washington seed lots tested positive for the RRA gene. *Ibid.* Because the company did not have any access to RRA seed at the time, it attributed the contamination to external sources. *Ibid.*

Petitioners blamed the first Cal/West contamination on human error and the second on "unintentional mixtures between transgenic and conventional seed and/or plants." Pet.App.405a-406a. But whatever the cause, the evidence demonstrated multiple examples of contamination, even when RRA was grown on a small scale.

c. *The mere duplication of preexisting contractual obligations in APHIS's proposed injunction requirements.* APHIS's proposed injunction incorporated provisions that were virtually identical to those in petitioners' contracts. See Pet.App.184a-187a; JA 376-78, 1062. For example, APHIS proposed that RRA grown for seed production be planted either 1500 feet or three miles from conventional alfalfa seed fields when leafcutter bees or honey bees, respectively, were used to pollinate the RRA. Pet.App.186a.

APHIS further proposed that the injunction require "pre-bloom" harvest of any RRA hay field within 165 feet of a conventional alfalfa seed field, and harvest "at or before 10% bloom" of any RRA field "located between 165 and 500 feet from any alfalfa field grown for seed production." *Ibid.* APHIS's measures replicated contractual requirements for RRA storage and equipment cleaning, as well. Pet.App.187a.[3]

Given that APHIS's proposed requirements for the injunction mirrored contractual obligations that had proven ineffective in preventing contamination, it is hardly surprising that the evidence also refuted the notion that APHIS's proposed measures would have averted the documented contamination events at Dairyland and Cal/West. For example, APHIS's injunction would have mandated only a 1500-foot isolation distance around the RRA fields adjacent to the Dairyland seed fields, Pet.App.186a, yet contamination was detected up to 1.5 miles away. JA 1018.[4]

d. *The evidence of APHIS's limited enforcement ability.* The record also established that there were severe constraints on APHIS's enforcement capabilities. The agency's own inspector general noted deficiencies in both the notification and permitting

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[3] APHIS's proposed injunction also provided that "RRA shall not be used for livestock grazing purposes" and that "all RRA seed producers and hay growers must be under contract with Monsanto or [FGI]," where those contracts "require compliance with [APHIS's] conditions." Pet App.187a.

[4] APHIS's prescribed isolation distance for leafcutter bee-mediated pollination (1500 feet) was far smaller than the flight ranges of wild honey bees or bumble bees, which can fly (and transport pollen) many miles. See, *e.g.*, JA 155, 383, 541.

processes and concluded that both failed to provide adequate oversight. *OIG Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits* (Dec. 2005) (Dkt. 95, Exh. A).[5] For example, the agency was often unaware of planting locations, *id.* at 14; field inspections, necessary to "ensure that planted GE crops do not persist in the environment," were grossly inadequate, *id.* at 27; and field test progress reports, necessary to track environmental impacts, were insufficient, *id.* at 35.[6]

Neil Hoffman, the Director of the Environmental Risk Analysis Division for APHIS, confirmed that resource constraints would continue to hamstring the agency's enforcement efforts. He admitted that it "would pose unusual challenges to [the agency's] current regulatory structure and significantly drain [agency] resources" to inspect even the 220,000 acres of already-planted RRA, let alone the projected five-fold increase in acreage predicted by petitioners in the two years required to prepare an EIS. JA 362, 437; see also JA 609-10, 621 (petitioners estimated that nearly 900,000 additional acres of RRA would be planted in 2007 and 2008).

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[5] This report was submitted to the district court with the declaration included at JA 395.

[6] In response to APHIS's repeated failures in containing genetically engineered crops, Congress enacted legislation in 2008 requiring APHIS to improve its oversight and take corrective measures to remedy past errors. See Pub. L. No. 110-234, Tit. X § 10204, 122 Stat. 923, 1343-44 (2008); Pub. L. No. 110-246, Tit. X § 10204, 122 Stat. 1651, 2105 (2008).

e. *The evidence concerning the effects of unpredictable weather, human error, inadequate equipment cleaning, inexact harvesting practices, and "wild" alfalfa and pollinators.* In many other ways, the evidence also called into question the efficacy of APHIS's proposed injunction conditions. For example, although APHIS proposed to require that all RRA hay fields be harvested before bloom, Pet.App.186a, both APHIS and petitioners candidly acknowledged that unpredictable weather – notably, summer thunderstorms – often precludes compliance with this critical requirement. JA 251, 553-54, 630. And allowing RRA hay fields to bloom substantially increases the probability of hay-to-hay or hay-to-seed gene transmission. See, *e.g.*, Pet.App.344a-345a, 355a.[7]

The record also showed that human error could cause inadvertent contamination. Seeds may spill during transport, causing patches of genetically modified alfalfa (not subject to isolation distances) to appear along roadsides, in ditches, or even among conventional or organic crops. *E.g.*, JA 458, 1007; see also JA 850-52. Or, as noted by FGI's president, accidental seed mixing easily can occur within a seed processing facility, notwithstanding efforts to properly segregate organic and genetically altered seed. Pet.App.405a; JA 407-08; see also JA 693-94.

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[7] The record also established that other uncontrollable events increased the likelihood of contamination. For example, flooding – either weather-related, or due to other causes – may cause newly planted RRA seed to be distributed across nearby properties, including fields of conventional or organic alfalfa. *E.g.*, JA 1002.

Several declarants noted that inadequate equipment cleaning also may cause contamination, because the typical "once overs" given to farm equipment by busy operators cannot remove every seed left in the machines. See JA 236-37, 1007. And growers are unlikely to employ the only cleaning procedures that could entirely eliminate the possibility of contamination: completely dismantling all harvesting equipment, a time-consuming and expensive proposition in the middle of harvest season. JA 642-43.

Declarants stated as well that common hay harvesting practices may lead to contamination. Although RRA growers may intend to harvest their entire field prior to bloom, tractors frequently miss plants at the edges of fields and may be unable to cut hay growing in wet spots, center pivots, or corners. JA 407, 1003, 1006, 1024. Moreover, growers may determine that it is not worth the time and resources to harvest the last cutting, which in turn may allow these plants to go to seed. JA 700, 1003.

In addition, many growers cannot afford to purchase their own harvesting equipment, so they hire "custom cutters" to harvest their crop. *E.g.*, JA 236-37, 629, 641-43. But these individuals are in high demand and may not be able to cut all of the fields before the plants begin to bloom, especially with inclement weather approaching. JA 641-43, 1006-07. If the custom cutters work in both RRA and conventional fields and, again, fail to completely clean their machines between uses – a likely scenario, as discussed above – it is extraordinarily likely that RRA pollen or seeds will be transferred to subsequently cut conventional fields. JA 1006-07; see also JA 642.

Evidence also indicated that APHIS's proposed conditions would not protect against contamination via "wild" or feral alfalfa, which is frequently found in abandoned fields or planted along roadsides. JA 108-09, 215.[8] Wild pollinators, including wild honey bees and bumble bees (which petitioners' own studies documented in large numbers alongside "stocked" bees in alfalfa fields) create a further risk of cross-pollination. *E.g.*, JA 383, 387, 534-35; see also JA 144-45, 635, 697-98, 1002-03. Indeed, one of the studies cited by petitioners noted that native honey bees and bumble bees (which may range up to five miles) were abundant in seed production fields. JA 389-90, 463-64, 534-35; see JA 635, 698.

f. *The evidence of contamination of other crops.* The record also documented contamination involving other genetically modified crops and grasses, including corn, canola, rice, soybeans, and bentgrass. *E.g.*, JA 139, 693-97, 741-45, 859-66, 884-971. Experiences with these other crops demonstrated the relative futility of containment initiatives and highlighted the potential for human error or other unknown factors to cause unintentional, widespread dissemination of new genetic material. *E.g.*, JA 693-97, 741-45, 859-66, 884-86, 965-71; see also JA 139.

g. *The district court's decision.* After conducting another lengthy hearing on April 27, 2007, the district court entered a permanent injunction. Pet.App.60a-79a. The court noted that "an injunction

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[8] Petitioners and their experts acknowledged that feral alfalfa may significantly contribute to cross-contamination. JA 458, 528, 574, 1056-57; Pet.App.237a-239a.

does not automatically issue" based on "a finding of a NEPA violation"; rather, because "injunctive relief is an equitable remedy," a court must "engage in the traditional balance of harms analysis." Pet.App.65a. The court observed that in a "run of the mill NEPA case," the "balance of harms" often "favor[s the] issuance of an injunction," because environmental injury "can seldom be adequately remedied by money damages and is often permanent or at least of long duration." Pet.App.65a-66a. The court also explained, however, that in certain circumstances an injunction may not be warranted. Pet.App.66a.

Next, "[a]fter carefully reviewing [the] voluminous evidence," Pet.App.67a, the court found that "plaintiffs have sufficiently established irreparable injury and that the balance of the equities weighs in favor of maintenance of the status quo," which (given the Court's prior invalidation of APHIS's deregulation decision) included the prohibition on further planting of RRA, Pet.App.71a; see also *id.* at 75a ("after balancing all of the equities, the Court in its discretion finds that an injunction maintaining the status quo * * * is appropriate"). Critical to the court's finding of a likelihood of irreparable injury was (1) the uncontested evidence that contamination *had already occurred*, notwithstanding petitioners' contractual requirements, and (2) APHIS's acknowledgement that it lacked the resources to enforce the usage conditions it had proposed, even if planting did not increase as dramatically as petitioners projected. Pet.App.69a-71a.

The district court therefore "(1) vacat[ed] the June 2005 deregulation decision; (2) order[ed] the govern-

ment to prepare an EIS before it [made] a decision on [the RRA] deregulation petition; [and] (3) enjoin[ed] the planting of any [additional RRA] in the United States * * * pending the government's completion of the EIS and decision on the deregulation petition." Pet.App.79a, 108a-110a.[9] By its own terms, the injunction will terminate when the EIS issues. Pet.App.108a. That will occur imminently; the period for comments on the draft EIS closed on March 3, 2010. 75 Fed. Reg. 8,299-8,300 (Feb. 24, 2010).

D. The Court Of Appeals Proceedings

APHIS and the intervenors appealed the permanent injunction. Neither, however, challenged the finding of a NEPA violation or the vacatur of the deregulation decision. C.A. Pet. Br. 1-2; C.A. U.S. Br. 2 (stating that the injunction was the "sole issue on appeal").

The Ninth Circuit affirmed, Pet.App.80a-103a, and after petitioners alone sought rehearing *en banc*, the Ninth Circuit affirmed in an amended opinion, Pet.App.1a-26a. The court stated that the district court had properly "applied the traditional four-factor test, required by *eBay* [v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006)]" (Pet.App.13a) – a test, the appeals court noted, that "applies in the environmental context," as in any other, Pet.App.11a. In particular, the district court had *not* "presume[d] that irreparable harm was likely to occur only on the basis of the

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[9] At the same time, the court allowed previously planted RRA to be harvested under conditions proposed by APHIS and expressly authorized APHIS's process for issuing permits governing regulated articles. Pet.App.76a-78a, 108a.

NEPA violation"; rather, the district court had found "that genetic contamination was sufficiently likely to occur so as to warrant broad injunctive relief." Pet.App.13a. After reviewing the record evidence, the court of appeals determined that the lower court's finding concerning the likelihood of irreparable injury "was not clearly erroneous." Pet.App.14a. Finally, the Ninth Circuit held that the district court had not abused its discretion in declining to conduct a trial-type evidentiary hearing. Pet.App.18a-19a.[10]

INTRODUCTION AND SUMMARY OF ARGUMENT

This is an extraordinary case, but not because the courts below departed from well-settled legal principles. They didn't. Petitioners start with the faulty premise that a recalcitrant court of appeals created a special exemption for plaintiffs in environmental cases, under which an injunction may issue even if irreparable harm is unlikely. There was no such holding by the courts below, and respondents neither seek nor rely on any such exemption. Petitioners briefly do battle with this straw man, then devote most of their brief to their request that this Court reweigh hundreds, if not thousands, of discrete facts and second-guess the district court under an abuse of discretion standard. And, remarkably enough, petitioners do all this in the service of a claim – that the injunction should be vacated or narrowed – that would avail them nothing even if successful.

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[10] On this last point only, Judge Smith dissented. Pet.App 20a-26a.

Indeed, if anyone is seeking to plow new legal ground, it is petitioners. They contend, for example, that only *species-level* effects are cognizable under NEPA, and thus there cannot be irreparable harm in this case. Elsewhere, they assert that contamination of alfalfa does not affect the "human environment," and, for that reason as well, the proven harms in this case cannot give rise to a NEPA injunction. Of course, these claims (and others) are hard to square with petitioners' acknowledgement that *some* form of injunction – in particular, the version they like – should be entered. More fundamentally, however, these contentions would, if accepted, eviscerate the purposes of NEPA and contravene its implementing regulations. There is no good reason to go down that path, and every good reason not to.

I. First things first: This Court should dismiss the case because petitioners lack standing to pursue this appeal. Petitioners have chosen to challenge *only* the district court's injunction, not its vacatur of APHIS's deregulation decision. But the vacatur had the undisputed effect of restoring RRA's status as a regulated article under the PPA. Standing alone, the vacatur remedy – which was proposed by the government and never contested by any party – independently prevents petitioners' sale or distribution of RRA. The injunction challenged in this Court therefore causes no independent injury to petitioners' legally cognizable interests, nor would a favorable ruling from this Court provide petitioners with any redress. The Court should decline petitioners' request to decide an abstract question that has no real-world consequences for them. Even if the Court concludes that the standing issue is debatable, it should

dismiss the petition as improvidently granted given the at best insubstantial effect on petitioners of the challenged injunction, which in any event will expire by its own terms in the very near future once an EIS is issued. With so little truly at stake, this Court's scarce resources could be directed to better uses than deciding whether the district court abused its discretion in resolving the highly fact-specific and record-dependent issues that are actually presented in this case.

II. If it reaches the merits, this Court should affirm the injunction issued by the district court. Neither petitioners nor the federal respondents have identified a genuine legal error committed by the courts below. Petitioners' claim, in substance, is that the lower courts *must* have committed legal error somewhere, because how else could they have lost? In support of that audacious claim, the best petitioners can do is to insist that isolated statements by the district court, ripped from context, reflect the application of an improper legal presumption or a "special NEPA exception" to the traditional injunction standards. Petitioners are simply mistaken about the nature of the district court's decision.

When all is said and done, what petitioners, the federal respondents, and their *amici* are asking this Court to do is to reweigh the "voluminous evidence" (Pet.App.67a) and enter a more limited remedy (though the remedy they seek also would include vacatur of the deregulation decision, a ruling petitioners have not challenged). But this request should be denied, as well, because the evidence amply supports the district court's conclusion that the harm in ques-

tion – genetic contamination of conventional and organic alfalfa – was both likely and irreparable. Moreover, petitioners' argument that the district court should have imposed APHIS's proposed injunction fails for multiple reasons, not least of which is that doing so would have violated binding federal regulations. Finally, if, contrary to our submission, the Court determines that the Ninth Circuit relied on a flawed legal analysis, the proper remedy would be to correct that error and remand to the court of appeals to redo its abuse-of-discretion review.

III. This Court should not strip district courts of their traditional discretion regarding the nature and content of injunctive hearings. The ironclad rule sought by petitioners – which would mandate trial-type proceedings before an injunction could be imposed – would do just that. It is unsupported by precedent, strays from the historical practices in equity, and would be particularly inappropriate in a case such as this, where the district court conducted multiple hearings and gave the complaining litigants every opportunity to present unlimited evidence in written form. At a minimum, if the Court finds that petitioners have a right to present live testimony and conduct cross-examination, the appropriate remedy is to remand for additional proceedings, not simply enter the injunction petitioners prefer.

ARGUMENT

I. PETITIONERS LACK STANDING TO PURSUE THIS APPEAL

This case should be dismissed at the threshold, because petitioners do not have standing. After concluding that APHIS violated NEPA, the district court

entered a judgment (1) vacating APHIS's deregulation decision, and (2) enjoining the planting of RRA pending completion of an EIS. But petitioners appealed from, and now challenge, only the propriety of the *injunction*, not the vacatur. As a consequence, even were this Court to vacate or narrow the injunction, petitioners would be in precisely the same position they are in today. Their distribution of RRA would still be unlawful because the vacatur restored RRA to its status as a regulated article, the distribution of which is unlawful under the PPA and APHIS regulations.[11]

The "irreducible constitutional minimum of standing" requires (1) a concrete and particularized injury in fact, in the form of an "invasion of a legally protected interest"; (2) a "causal connection between the injury and the conduct" of which a litigant complains, such that the alleged injury is "fairly * * * trace[able] to the challenged action"; and (3) a demonstration that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992) (citation omitted). Petitioners fail to satisfy any of these requirements.[12]

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[11] The district court carved out from the injunction a narrow protection for farmers who had already begun planting or had purchased seed intending to plant. Pet.App.58a. Respondents opposed that exception, see Pl.'s Proposed Judgment (Dkt. 93, Att. 2, filed Mar. 2, 2007), but elected not to challenge the issue on appeal

[12] A party must satisfy standing requirements to pursue an appeal. *Arizonans for Official English* v. *Arizona*, 520 U.S. 43, 64 (1997) ("The standing Article III requires must be met by

Because petitioners do not challenge the vacatur of the deregulation decision, the injunction, standing alone, cannot impair petitioners' interest in distributing RRA without a permit. When the deregulation decision was vacated, RRA reverted to its status as a "regulated article." Pet.App.58a. Petitioners and the government acknowledge that it is unlawful to distribute such "regulated articles" (unless either for field testing or pursuant to a permit issued by APHIS, both of which are *authorized* under the district court's judgment). Pet. Br. 7-8; U.S. Br. 1-3. Indeed, petitioners sought intervention in the district

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persons seeking appellate review, just as it must be met by persons appearing in courts of first instance."). In addition, petitioners as intervenors are required to show that they have standing at this stage of the proceeding because they are the only parties that sought this Court's review of the Ninth Circuit's decision. See *Diamond* v. *Charles*, 476 U.S. 54, 68 (1986) (intervenors who invoked this Court's appellate jurisdiction must demonstrate Article III standing where the defendant State, although a party in the court of appeals, did not take its own appeal but merely filed a letter in this Court stating it wished to receive the same relief as the intervenor). For these reasons, there is no need for this Court to decide whether the federal respondents had standing to take an appeal of the district court's injunction. There is, however, significant reason to doubt that such standing exists. To the extent that the government asserts harm arising from the injunction against expanded distribution of RRA, it is in the same boat as petitioners; given the unchallenged vacatur order, the injunction causes no injury to a legally protected interest of APHIS that could be redressed by a favorable decision. And to the extent that the injunction contains provisions that impose special requirements or prohibitions on the government (such as that APHIS promulgate an administrative order to regulate previously planted and harvested RRA), those provisions were *proposed by the government itself*. JA 376; Pet.App.184a.

court in part because "[r]escission of the USDA deregulation decision * * * could effectively bar further sales" of RRA. Mot. To Intervene filed by Monsanto Co. at 13 (Dkt. 86, filed Mar. 2, 2007).

Thus, rather than asserting harm to a "legally protected interest," petitioners assert only an interest that has already been determined to be legally *unprotected* – indeed, an interest in engaging in activity that is unlawful under the PPA. Moreover, that determination is not subject to review by this Court. Petitioners did not object to the vacatur remedy in the district court (even after acknowledging, in seeking intervention, that rescission of the deregulation decision would make it unlawful to distribute RRA); did not appeal that portion of the remedy; did not describe it in their Questions Presented; and do not contest the vacatur in their merits brief.

Petitioners also flunk the second requirement for standing: the prevailing restrictions on their sale and distribution of RRA are not "fairly traceable" to the district court's injunction. *Allen* v. *Wright*, 468 U.S. 737, 751 (1984). On the contrary, those restrictions are traceable to the unchallenged vacatur order. Put differently, the *challenged* injunction adds nothing to the restrictions on petitioners that flow independently from the *unchallenged* vacatur decision. Where the line of causation is too attenuated, *i.e.*, "the injury [to the complaining party] is highly indirect," standing is absent. *Id.* at 757 (citing *Simon* v. *E. Ky. Welfare Rights Org.*, 426 U.S. 26, 42 (1976)). Here the causal connection is not only "weak" (*id.* at 759) but nonexistent.

Finally, petitioners must show that they will "benefit in a tangible way from the court's intervention." *Steel Co.* v. *Citizens for a Better Env't*, 523 U.S. 83, 103 n.5 (1998) (citation omitted). Where a party does not "stand to profit in some personal interest," *Simon*, 426 U.S. at 39, or where it is "speculative" whether the judgment will result in relief, *id.* at 42-43, that party lacks "such a personal stake in the outcome of the controversy as to warrant [its] invocation of federal court jurisdiction and to justify exercise of the court's remedial powers on [its] behalf," *id.* at 38. That principle applies with full force where, as here, a party challenges one prohibition on its conduct, but does not challenge a second independent prohibition that bars the same conduct. See, *e.g.*, *Renne* v. *Geary*, 501 U.S. 312, 319 (1991) (doubtful that injury is redressable when challenged conduct is prohibited by separate, unchallenged statute); *Covenant Media of S.C., LLC* v. *City of N. Charleston*, 493 F.3d 421, 430 (4th Cir. 2007), *cert. denied*, 552 U.S. 1100 (2008) (plaintiff lacked standing to challenge constitutionality of regulation because separate, unchallenged regulation prohibited the same conduct); cf. *Coleman* v. *Thompson*, 501 U.S. 722, 729 (1991) (Court will not review question of federal law decided by a state court when judgment below is supported by an adequate and independent state law ground).

Quoting a prominent legal philosopher, the Chief Justice succinctly summarized standing principles: "When you got nothing, you got nothing to lose." *Sprint Commc'ns* v. *APCC Servs., Inc.*, 128 S. Ct. 2531, 2550 (2008) (Roberts, C.J., dissenting). The converse is also true. If "you got nothing to lose" from

the entry of an injunction, and nothing to gain if the injunction is vacated, "you got nothing."[13]

For these reasons, the Court should dismiss the case for want of standing. But even if the Court concludes that standing is debatable, it should dismiss the petition as improvidently granted. At best, the injunction has a negligible real-world effect on petitioners – and it is poised to expire in the immediate future when APHIS issues its EIS, which could happen any day. These circumstances certainly do not warrant this Court's fact-intensive re-examination of the record to decide issues that, as we explain below, are not the clear-cut legal questions framed in the petition but rather are highly case-specific issues subject to the trial court's broad equitable discretion and reviewable on appeal only for abuse of discretion.

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[13] For obvious reasons, petitioners have never suggested that they intend to defy the injunction by taking actions that would also violate federal law (the PPA and APHIS regulations) and trigger criminal penalties and other administrative sanctions. See 7 U.S.C. § 7734 (criminal and civil penalties under the PPA); 7 C.F.R. § 340.0(b) n.2 (remedial powers of APHIS). Nor could petitioners, by declaring such an implausible intent, create a basis for their own standing by conjuring up the specter of contempt. See *Lujan*, 504 U.S. at 560 (standing requires an injury that is "concrete and particularized," "actual or imminent," and not merely "conjectural or hypothetical") In any event, such an assertion by petitioners of an intent to flout the injunction would be powerful evidence of unclean hands and thus would provide an independent ground for affirming the equitable remedy entered below.

II. THE COURT OF APPEALS CORRECTLY HELD THAT THE CHALLENGED INJUNCTION WAS NOT AN ABUSE OF DISCRETION

Petitioners assert that this case presents the following questions: (1) whether "NEPA plaintiffs are specially exempt from the requirement of showing a likelihood of irreparable harm to obtain an injunction," and (2) whether an injunction may be affirmed if "based on only a remote possibility of reparable harm." Pet. Br. i. They further contend that, in order to affirm the judgment of the district court, the court of appeals necessarily disregarded or created a new exception to the traditional four-part test for injunctive relief.

These arguments are utterly lacking in merit. The lower courts did not even *suggest* that NEPA plaintiffs fall within a special "exception" to the traditional test for injunctive relief or that a "presumption" of harm arises in NEPA cases. Nor did either court give *any* indication that, in its view, the harm in question was merely "possible," but not "likely." And certainly neither court stated that an injunction premised on such a finding would be permissible under this Court's precedent. In fact, both courts below articulated and faithfully applied the correct legal standards.

Once petitioners' imagined legal errors are set to one side, it is clear that the Ninth Circuit correctly concluded that the district court did not abuse its discretion in entering the injunction. The district court's findings concerning irreparable harm were amply supported in the record and not clearly erroneous. Its

careful weighing of the traditional equitable factors was beyond reproach, and certainly not an abuse of discretion. And its decision not to impose the conditions proposed by APHIS was supported by good reasons that petitioners and the federal respondents simply ignore.

A. The Lower Courts Applied The Correct Legal Standards

1. Both courts below acknowledged and applied the traditional, four-factor test for determining the propriety of injunctive relief

It is common ground that a plaintiff seeking a permanent injunction must satisfy the traditional, four-part equitable test by showing that (1) "he is likely to suffer irreparable harm," *Winter*, 129 S. Ct. at 374, (2) "remedies available at law, such as monetary damages, are inadequate to compensate for [the] injury," *eBay*, 547 U.S. at 391, (3) "the balance of equities tips in his favor," *Winter*, 129 S. Ct. at 374, and (4) "an injunction is in the public interest," *ibid.* In affirming the district court, the Ninth Circuit expressly acknowledged this governing test, Pet.App.11a, and unambiguously concluded that the district court had applied it, Pet.App.13a. That conclusion is unassailable. The district court expressly referred to the "traditional balance of harms analysis" and discussed each of the four factors in turn. See Pet.App.65a, 71a-72a (examining "irreparable injury," "irreparable environmental harm," "balance of the equities," and "harm to" certain farmers and consumers that "outweighs the economic harm to Monsanto"), 74a-75a (examining the "public interest"),

75a (deciding "after balancing all of the equities" that injunctive relief was warranted).

Although petitioners concede that "the Ninth Circuit articulated the showings that must be made under the traditional equitable test, and acknowledged that the test applies in environmental cases," they claim that "when the rubber met the road," the court of appeals in fact dispensed entirely with the first factor – likelihood of irreparable harm – by applying a "presumption of irreparable harm * * * [in] NEPA cases." Pet. Br. 28-29. As for the district court, petitioners fault it for "advert[ing] to the traditional equitable factors * * * only cursorily" and for concluding that respondents had "'*sufficiently* established irreparable injury'" (a phrase that petitioners interpret as adopting an impermissible "possibility of irreparable harm" standard instead of the traditional "likelihood of irreparable harm" standard). Pet. Br. 18 (quoting Pet.App.71a).

Petitioners' principal evidence for this claim is the district court's statement that "'[i]n the run of the mill NEPA case, the contemplated project * * * is simply delayed until the NEPA violation is cured,' that is, the balance of harms favor[s] issuance of an injunction." Pet.App.65a (quoting *Idaho Watersheds Project* v. *Hahn*, 307 F.3d 815, 833 (9th Cir. 2002)). But that observation hardly reflects a "presumption of irreparable harm." Pet. Br. 22. It is, instead, an accurate empirical observation about the circumstances that frequently warrant injunctive relief. Indeed, petitioners' own attorney told the trial court that in "the run of the mill NEPA case, * * * environmental injury" is "likely." Tr. of April 27, 2007

Hearing at 17. And the federal respondents have made the very same observation in this case, pointing out that, "[a]s a matter of practical experience, cases involving claims of significant harm to the environment may result in injunctive relief more often than private litigation involving economic or other interests." U.S. Br. 20.[14]

Moreover, the remainder of the district court's opinion reflects careful analysis of each element of the traditional test for injunctive relief and belies any suggestion that the court applied an incorrect legal standard. First, the court noted the many reasons why cross-contamination was likely to recur absent an injunction. Pet.App.69a-71a; see also pages 11-13, *supra*. It found the interim conditions proposed by

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[14] Petitioners and the federal respondents complain as well about the district court's comment that "in unusual circumstances an injunction may be withheld, or, more likely, limited in scope." Pet.App.66a (quoting *Nat'l Parks & Conservation Ass'n* v. *Babbitt*, 241 F.3d 722, 737 n.18 (9th Cir. 2001) (quotation omitted), see Pet. Br. 16; U.S. Br. 21. Once again, however, this passage is simply an empirical account of the frequency of injunctive relief in environmental cases. And Members of this Court recently have emphasized that a "historical practice" of granting injunctive relief in a particular type of case should be accorded some weight. *eBay*, 547 U.S. at 395 (Roberts, C.J., concurring); *id.* at 395-96 (Kennedy, J., concurring) ("The Chief Justice is * * * correct that history may be instructive in applying th[e] test [for injunctive relief]."). Courts deciding whether to issue injunctive relief are not "writing on an entirely clean slate" and should be mindful of "the basic principle of justice that like cases should be decided alike. When it comes to discerning and applying [legal standards governing equitable discretion], * * * a page of history is worth a volume of logic." *Id.* at 395 (Roberts, C.J.) (internal citations omitted).

APHIS "similar to those already imposed" by contract, and observed that "contamination has occurred" in four states "despite those conditions." Pet.App.70a; see also pages 7-8, *supra*. It rejected the contention that APHIS's conditions might be more effective than the contractual requirements in preventing contamination, given that APHIS had acknowledged that it lacked "the resources to inspect the 220,000 acres currently planted with [RRA] hay," let alone "the more than one million acres of [RRA] hay" and the "concomitant increase in seed acreage" that petitioners "estimate will be planted" absent an injunction. Pet.App.70a; see also pages 9-10, *supra*. In addition, the court cited concessions from the president of FGI that uncontrollable factors, such as weather, can prevent farmers from harvesting alfalfa forage crop before seeds mature. Pet.App.71a; see also page 11, *supra*. The court also considered other circumstances that could impair the effectiveness of APHIS's proposed conditions, including human error, inadequate equipment cleaning, inexact harvesting practices, and "wild" alfalfa and pollinators. See pages 11-13, *supra*. Finally, the court observed that the injury caused by genetic contamination was irreparable, in part because "contamination cannot be undone" once it occurs. Pet.App.71a.

Next, the district court found that "[t]he harm to these farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa." Pet.App.71a. In particular, it observed that any RRA seed would survive in storage, unharmed, until

APHIS completed the EIS. Pet.App.72a. Moreover, it found that any lost revenue to petitioners did "not outweigh the potential irreparable damage to the environment." *Ibid.* Nor did "[t]he desire of some farmers to plant *more* [RRA] or to *switch* to [RRA] * * * outweigh the potential for irreparable harm." *Ibid.* Finally, the court noted that petitioners' proposed "expansion of the [RRA] market pending the preparation of the EIS" was "unprecedented" and was not in the public interest. Pet.App.72a-75a.

In short, the district court demonstrated that it understood and correctly applied the traditional test for injunctive relief, including the requirement of likely irreparable harm. Petitioners' attempts to transmute that court's reasoned analysis into legal error – by suggesting an interpretation of its opinion that the court itself clearly did not intend – are entirely unavailing.

2. The lower courts did not create a "NEPA exception" to the traditional legal standard for injunctive relief

According to petitioners, the district court created – and the court of appeals affirmed – "a special NEPA exception to the rule that an injunction will not issue except as necessary to prevent a likelihood of irreparable harm." Pet. Br. 31. These arguments again misrepresent the analysis employed by the lower courts.

As discussed above, the district court painstakingly explained why contamination was likely to occur in the future absent an injunction. In doing so, it did not rely on its prior holding on the merits of the NEPA claim. Rather, the court simply stated that, in

its previous opinion, it had found (just as it had a mere page before in its order on injunctive relief) that "contamination * * * has occurred and defendants acknowledge as much." Pet.App.71a. Then, in the remainder of its order, the court independently stated (1) why contamination was likely to recur absent an injunction; (2) why contamination constituted irreparable injury; and (3) why the other traditional factors counseled in favor of injunctive relief. Pet.App.69a-75a.[15] None of this analysis, of course, would have been necessary if the court had adopted the "NEPA exception" claimed by petitioners. From the face of the district court's opinion, then, it is plain that the court understood its obligation to consider all of the equitable factors and did *not* conclude that irreparable harm was likely to occur solely on the basis of the NEPA violation.[16]

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[15] To the extent petitioners' and the federal respondents' argument is premised on the notion that past contamination events did not constitute irreparable injury, their own briefs refute that claim. Both acknowledge that *some* measure of injunctive relief is warranted, and petitioners specifically request that this Court enter "the tailored *injunction* proposed by APHIS." Pet. Br. 25 & n.9. 57 (emphasis added), U.S Br. 32-33. That relief presupposes that there is at least some degree of irreparable harm.

[16] Although cast as a distinct claim, petitioners' assertion that the courts below erred in requiring a showing only of a "possibility" of harm merely repeats the same arguments they employed in suggesting that the courts improperly presumed harm or created a "NEPA exception" to the traditional injunctive standard See Pet. Br. i, 33. This case simply does not present the same legal error that arose in *Winter*, 129 S. Ct. 365.

3. The court of appeals applied the correct legal standards in upholding the injunction

Petitioners and the federal respondents concede that the court of appeals "set forth the correct legal standard." U.S. Br. In Opp. 10, 13; Pet. Br. 28. Indeed, the Ninth Circuit could hardly have been clearer in explaining the traditional four-part test for injunctive relief, and it expressly recognized that the test applies in NEPA cases. Pet.App.11a-12a (citing *Amoco Prod. Co.* v. *Village of Gambell*, 480 U.S. 531, 545 (1987)). The court of appeals also correctly observed that "an injunction does not automatically issue when a NEPA violation is found." Pet.App.13a. Citing this Court's recent decision in *Winter*, the court recognized that plaintiffs must demonstrate a *likelihood*, not a mere possibility, of irreparable harm to obtain an injunction. *Ibid.* The Ninth Circuit's analysis is based upon sound legal principles.[17]

In an effort to locate a viable criticism, petitioners are reduced to invoking snippets of language in the court of appeals' opinion that have nothing to do with whether the traditional equitable factors were satisfied. Thus, they fault the Ninth Circuit for stating

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[17] Not surprisingly, petitioners' *amici* have trouble articulating the court of appeals' legal error, as well. One *amicus* acknowledges, for example, that "[t]he lower courts accurately recited the basic four-factor test for issuance of a permanent injunction," but insists that they were only "paying lip service to the established standard," Br. of Am. Farm Bureau *et al.* 7, in an effort to "camouflage[]" their defiant "attitude," *id.* at 15. Absent *actual* legal error, however, improper "attitude" does not justify reversal.

that the district court "did not believe defendants had established any [disputed] material issues of fact" and "viewed the disputed matters to be issues more properly addressed by the agency." Pet.App.17a-18a; Pet. Br. 29. These statements, petitioners claim, demonstrate that the court of appeals (1) believed that the district court issued an injunction "without adjudicating the likelihood of irreparable harm," and (2) affirmed that decision because, like the district court, it considered "the agency's impending EIS process as a substitute for judicial weighing of the traditional equitable standards for injunctive relief." Pet. Br. 29.

The cited passages, however, have *nothing* to do with the appellate court's assessment of the traditional equitable factors. In fact, in the pages *preceding* these quotes, the court had *already* explicitly held that the district court's weighing of those factors – including, in particular, its consideration of irreparable harm – did not reflect an abuse of discretion. Pet.App.13a-16a. The quoted statements, by contrast, are located in the section of the court's opinion addressing whether petitioners were entitled to an evidentiary hearing. Pet.App.16a-20a. They justified an entirely distinct holding that in no way establishes a rule allowing district courts ever to forego consideration of any of the equitable factors.

Petitioners go through similar analytical somersaults in insisting that the court of appeals (despite what it clearly said) intended to create a "NEPA exception" to the irreparable harm requirement. Pet. Br. 32. In that connection, they point to the Ninth Circuit's observation that an "injunction to ensure

compliance with NEPA has a more limited purpose and duration" than one issued under other circumstances, and the lower court's conclusion that, because of the limited temporal nature of the relief here, an evidentiary hearing was not necessary, even if different circumstances might demand otherwise. Pet.App.18a-19a. Once again, this error is completely contrived; as before, the cited passages addressed whether an evidentiary hearing was required, *not* whether the injunctive factors had been satisfied.

Equally unfounded are petitioners' efforts to suggest legal errors similar to those corrected in *Amoco, Winter*, and *Romero-Barcelo*. In both *Amoco* and *Romero-Barcelo*, the appellate court had overturned a district court finding that an agency action had no significant environmental effect. In doing so, the court of appeals committed legal error by either presuming irreparable injury, *Amoco*, 480 U.S. at 544-45, or concluding that an injunction issues automatically upon a finding of a procedural violation, *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 311-23 (1982). Here, by contrast, the court of appeals made no legal error and merely *affirmed* the district court's fact-intensive analysis under a deferential abuse-of-discretion standard of review. And, unlike in *Amoco*, in particular, here there was no EIS from which the district court could have fairly concluded that the adverse environmental impacts in question were not likely or irreparable. See 480 U.S. at 544.

This case is also very different from *Winter*. The error in *Winter* was the application of an incorrect legal standard – the requirement of a mere "possibility" of harm. 129 S. Ct. at 375. Here, by contrast, there

was no misstatement of applicable law. But this, presumably, is why petitioners must go to such lengths to conjure one up. Without an erroneous "presumption" or "exception" to attack, the underlying premise of two of the three questions presented proves utterly unfounded. As Gertrude Stein famously said about Oakland, "there's no 'there' there." GERTRUDE STEIN, EVERYBODY'S AUTOBIOGRAPHY 289 (1937).

B. The District Court's Findings Concerning Irreparable Harm Were Well Grounded In The Record, And Its Decision Issuing Injunctive Relief Was Not An Abuse Of Discretion

Once petitioners' claims of legal error are properly disregarded, it is clear that their real complaints are merely challenges to the district court's findings, weighing of the evidence, and balancing of the equities. Indeed, petitioners themselves seem to concede as much, given the entirely new arguments that have appeared in their merits brief – arguments that one must squint to discern in the questions presented. For example, they now complain that the district court's true error was not in entering *an* injunction but in failing to enter the one *they* wanted. Thus, they ask this Court to remand with instructions to enter a brand new remedy that, they contend, better accounts for the weight of the evidence and the balance of equitable factors.

This request flouts the fundamental premise of abuse-of-discretion review. The reason appellate courts review equitable decisions under a deferential standard is to allow *district courts* to weigh the evidence and determine the remedy that is best suited to

the case. See *Gen. Elec. Co.* v. *Joiner*, 522 U.S. 136, 143 (1997) ("[D]eference * * * is the hallmark of abuse-of-discretion review."). Even if this Court were to accept petitioners' invitation to assume the role of the district court for itself, petitioners' argument should be rejected because the district court's decision reflected an entirely appropriate exercise of discretion.

1. The record confirms that injury arising from genetic contamination had occurred and was likely to recur absent an injunction

The record contains ample support for the district court's conclusion on the likelihood of irreparable harm. The evidence showed numerous instances of contamination of conventional alfalfa, even when RRA was planted on a small scale and subject to contractual requirements similar to those APHIS proposed for inclusion in the injunction. It showed, as well, that APHIS, by its own admission, was incapable of enforcing the conditions it proposed to prevent contamination. This evidence, which is summarized above (at pages 6-13, *supra*), will not be repeated here. The court of appeals correctly held that none of the district court's findings was clearly erroneous.[18]

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[18] The record demonstrates that contamination was more likely than not, but irreparable harm may be sufficiently "likely" without, of course, being "more likely than not." Especially in a case in which the agency has failed to prepare a required EIS, it would be passing strange to require private plaintiffs – bereft of the agency's findings – to make a "more likely than not" showing in order to preserve the status quo. Such a requirement also would conflict with this Court's precedent stating that parties

2. The district court properly concluded that genetic contamination constitutes irreparable environmental harm

Petitioners and the federal respondents both assert that contamination, even if likely, would not constitute "irreparable environmental harm." Pet. Br. 35-40; U.S. Br. 27-29. For many reasons, they are wrong.

a. Petitioners begin by asserting that genetic contamination of alfalfa is not a harm to the "human environment." Pet. Br. 35-37. That claim is not only implausible on its face but also an impermissible backdoor effort to relitigate the district court's unchallenged ruling on the merits of respondents' NEPA claim. The *environmental* nature of the injury is precisely the reason the district court found the EIS necessary in the first place.

Petitioners' argument is also flatly inconsistent with their own request that this Court "remand with instructions to enter [APHIS's] tailored *injunction*." Pet. Br. 25 n.9 (emphasis added); see also *id.* 47-50.

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need only demonstrate a "*sufficient* likelihood" of irreparable injury for an injunction to issue. *City of Los Angeles* v. *Lyons*, 461 U.S. 95, 111 (1983) (emphasis added); *Amoco*, 480 U.S. at 545 (environmental injury must be "*sufficiently* likely" for "the balance of harms" to "favor the issuance of an injunction to protect the environment" (emphasis added)). "Sufficient" hardly connotes "51 percent." What is more, whether injury is "sufficient" is clearly the appropriate standard, given the highly contextual inquiry necessary to issue equitable relief. A contrary standard would fundamentally change the nature of equitable proceedings and would undermine the ability of parties to obtain injunctive relief.

If petitioners concede – as they most certainly do – that *some* form of injunctive relief is required "to prevent irreparable harm," Pet. Br. 48, then they cannot seriously dispute that (1) some amount of harm is sufficiently likely absent an injunction, and (2) such harm is precisely the sort that NEPA addresses.

Furthermore, NEPA's implementing regulations emphasize that the phrase "[h]uman environment shall be interpreted comprehensively to include the natural and physical environment and the relationship of people with that environment." 40 C.F.R. § 1508.14. The harm identified here is unquestionably one that affects "the natural and physical environment," as well as "the relationship of people" – alfalfa growers – "with that environment." See *ibid.* If alfalfa plants themselves are irreversibly altered, and thus alfalfa growers are unable to derive benefit and profit from those plants, such injury certainly qualifies for relief.

b. Perhaps recognizing the futility of this first argument, petitioners try a second: even if environmental harm is likely, NEPA, they claim, recognizes only *species-level* effects. Pet. Br. 36; U.S. Br. 28-29. For numerous reasons, this argument falls short. To begin with, petitioners failed to raise it below. See C.A. Pet. Br. 49-59. It would be inappropriate for this Court to consider this argument when the lower courts were not afforded the opportunity to do so.

Moreover, even if it had been properly preserved, this argument is baseless. It defies common sense to suggest that *no* environmental harm has occurred unless a species is at risk of extinction. The argument also conflicts with NEPA regulations, which

specifically recognize that an action may require an EIS even if it has only *local* effects on the human environment. 40 C.F.R. § 1508.27(a) ("Significance varies with the setting of the proposed action. For instance, *in the case of a site-specific action, significance would usually depend upon the effects in the locale* rather than in the world as a whole." (emphasis added)).

Given the inconsistency with NEPA of petitioners' newfound "species-level harm" argument, it should come as no surprise that petitioners and the federal respondents together can muster only two cases that supposedly support it. See Pet. Br. 36-37 (citing *Fund for Animals* v. *Frizzell*, 530 F.2d 982 (D.C. Cir. 1975), and *Water Keeper Alliance* v. *Dep't of Defense*, 271 F.3d 21 (1st Cir. 2001)); U.S. Br. 28 (same). Both cases offer little legal support and are distinguishable for numerous factual reasons, most importantly because they address *isolated injuries* to *individual members* of an established species, not the dangers inherent in introducing a novel genetic trait into the ecosystem on a significant scale. The proven contamination incidents involving corn, canola, rice, and soybeans, all of which are well documented in the record, provide proof that once a plant species is infiltrated by unwanted genetic material, it is extraordinarily difficult to halt, let alone reverse, that effect. See, *e.g.*, JA 835-39, 870-73.

c. Petitioners next attempt to minimize the harm in question by characterizing it as "purely economic" and contending that "remedying such an economic harm is simply not one of NEPA's purposes." Pet. Br. 38. But the statute, as well as its governing regula-

tions, are quite clear that NEPA *is* concerned with "ecological * * * aesthetic, historic, cultural, *economic*, social, [and] health" effects, "whether direct, indirect, or cumulative." 40 C.F.R. § 1508.8 (emphasis added); 42 U.S.C. § 4331. To be sure, NEPA is not intended to address "economic or social effects * * * *by themselves*," but where, as here, those effects "are interrelated" with "natural or physical environmental effects," agencies must consider them in an EIS. 40 C.F.R. § 1508.14 (emphasis added).

Here, the economic effects are hardly speculative, as petitioners and the federal respondents now suggest. The record contains abundant evidence about the injuries that would befall conventional and organic alfalfa growers, dairy farmers, and livestock owners, if alfalfa crops were contaminated. JA 631, 636, 639-40, 643, 646-50, 652-54, 658-61, 664, 666-67, 974-98. The organic market demands "100% GE-free" products; organic consumers are likely to refuse to purchase products that contain even trace amounts of genetically engineered material. JA 103-04, 110, 124, 139, 449, 454, 638. Because the alfalfa export market can be equally demanding, contamination also threatens growers' international sales. Pet.App.262a; JA 127-30, 149-50, 409-11, 420-23, 623-24, 1070-71.[19]

These economic harms are also quite significant. As both petitioners and the federal respondents are constrained to acknowledge, those injured stand to

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[19] For example, when rice grown in the United States became contaminated with genetically engineered material, international demand for the product plummeted, costing many U.S. farmers their livelihood. See JA 696-97, 884-86.

lose the entire "organic premium" their product would otherwise command. Pet. Br. 38-39; U.S. Br. 27 & n.6. That loss alone would threaten the viability of their businesses, which depend on that premium to compensate for production costs that far exceed those associated with conventional methods. See, *e.g.*, JA 988-89. Even if such losses have yet to occur, courts routinely recognize that devastating *potential* economic injury warrants injunctive relief. See, *e.g.*, *Doran* v. *Salem Inn, Inc.*, 422 U.S. 922, 932 (1975); *Organized Village of Kake* v. *Egan*, 80 S. Ct. 33, 38 (1959) (Brennan, J., granting application for equitable relief in his capacity as circuit justice); *Gateway E. Ry. Co.* v. *Terminal R.R. Ass'n of St. Louis*, 35 F.3d 1134, 1140 (7th Cir. 1994).[20]

d. In any event, the harm to growers and livestock owners is not "purely" economic. As the district court observed, "[f]or those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop." Pet.App.44a. NEPA specifically seeks to "maintain

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[20] Petitioners' contrary argument relies heavily on their apparent misunderstanding of *Metropolitan Edison Co.* v. *People Against Nuclear Energy (PANE)*, 460 U.S. 766 (1983), which they say establishes that "the *risk* of harm is not" cognizable under NEPA. Pet. Br 37, 40. But the claims of mental health effects in *PANE* were non-cognizable because they were caused by the plaintiffs' *fear* of an environmental impact. *PANE*, 460 U.S. at 777-78. The Court made clear that NEPA is concerned with the *risks* of environmental impacts, *id.* at 775 & n.9. even if the *fear* of such risk is not cognizable. Here, the court found (and no party disputed) a classic *environmental* impact.

* * * an environment which supports diversity and variety of individual choice," 42 U.S.C. § 4331(b)(4), and it would contravene that important purpose to allow an agency's actions to eliminate or impair "a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food," Pet.App.44a.

e. Finally, petitioners and the federal respondents err in suggesting that the injuries in question are "reparable." Pet. Br. 38-39; U.S. Br. 27-28. A novel genotype that causes an *irreversible* effect on a plant species is hardly unprecedented. As previously explained, such effects have followed the introduction of numerous genetically engineered plant species. See JA 720-842, 855-83, 884-86, 965-73. Nor is it "bad science fiction," Pet. Br. 34, to believe that the introduction of a new plant or animal for beneficial purposes can backfire and lead to irreparable harm. Cf. Renewed Mot. for Prelim. Inj., Nos. 1, 2, and 3, Original, *Wisconsin* v. *Illinois* (U.S. filed Feb. 4, 2010) (requesting a preliminary injunction to require certain measures to protect Lake Michigan from Asian Carp, an invasive species first introduced for beneficial purposes, but which now poses a significant threat to critical waterways, as illustrated in http://www.youtube.com/watch?v=2ChwJiKKBdA&NR=1).

The injuries to growers and farmers also are irreparable. There is no remedy to farmers for their loss of choice to grow (or feed to their livestock) non-genetically engineered crops. And to the extent they suffer economic damages, it is doubtful, at best, that farmers will have adequate legal remedies. Federal

crop insurance regulations specifically disallow coverage for "[c]ontamination by application or drift of prohibited substances onto land on which crops are grown using organic farming practices * * *." 7 C.F.R. § 457.8 (provision 37(f)); see also JA 398-99, 654. And private lawsuits are likely to be stymied by the difficulty of locating the proper defendant, as well as the interposition of causation defenses ("it was the honey bees' fault").

3. The district court did not abuse its discretion in weighing the traditional equitable factors and other case-specific factors

Like any other proceeding in equity, an inquiry regarding the proper remedy for a NEPA violation is expressly committed to the district court's discretion. That decision, moreover, must account for an array of case-specific factors, all of which, in this case, strongly justified the district court's injunction – and confirm the inappropriateness of petitioners' request that this Court rebalance these considerations *de novo*.

First, this case arises in uncharted territory. No EIS has ever been completed on a genetically modified product. Agency counsel acknowledged that RRA is the first herbicide-resistant crop for which there is a risk of gene transmission to conventional crops. Pet.App.45a. Even among other genetically engineered crops, RRA is the first genetically engineered herbaceous perennial slated to be grown nationwide

in crop fields. JA 132, 140, 147.[21] Thus, this case stands in sharp contrast to *Winter*, in which plaintiffs sought "to enjoin – or substantially restrict – training exercises that have been taking place * * * *for the last 40 years*." 129 S. Ct. at 376 (emphasis added). There, the risks and effects of the Navy's activities were well known and documented in "a detailed, 293-page EA." *Ibid.* Here, by contrast, APHIS's meager, 41-page EA on the effects of deregulating RRA, JA 151-231, failed to provide the requisite "hard look at environmental consequences," *Kleppe* v. *Sierra Club*, 427 U.S. 390, 410 n.21 (1976) (quotation marks omitted), necessary to allow dramatic expansion of a new activity.

Second, as explained above, distribution of RRA had already caused undisputed incidents of contamination under conditions virtually identical to those proposed by APHIS. See Pet.App.404a-409a; see also pages 6-8, *supra*. Those contamination events occurred when just "one percent of the total alfalfa acreage in the United States" was devoted to RRA. JA 350. Given that petitioners projected a five-fold increase in RRA sales before the EIS was complete, it is all the more likely that their product would cause even greater injury to conventional and organic al-

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[21] Perennials increase the risk of contamination, because they live for several years and are hardier (*i.e.*, survive winters), making it more likely that feral plants could serve as contamination "bridges" between RRA and conventional plants. See, *e.g.*, JA 458. APHIS has approved one other perennial, a genetically modified papaya tree, JA 175, but that is not a row crop, is grown only in Hawaii, and does not present the same feral risks that alfalfa does.

falfa growers during that time. See JA 609-10, 621; see also page 10, *supra*.

The need to account for such case-specific factors is precisely why district courts have long exercised broad equitable discretion. See, *e.g.*, *Hecht Co.* v. *Bowles*, 321 U.S. 321, 329 (1944) ("The essence of equity jurisdiction has been the power of the Chancellor to do equity and mould each decree to the necessities of the particular case."); *Seymour* v. *Freer*, 75 U.S. (8 Wall.) 202, 218 (1869) ("[A] court of equity ha[s] unquestionable authority to apply its flexible and comprehensive jurisdiction in such manner as might be necessary to the right administration of justice between the parties."). Here, the district court's injunctive relief addressed "the necessities of the particular case," *Hecht*, 321 U.S. at 329, within the correct legal framework.

Ignoring these sound legal underpinnings and the unique elements of this case, petitioners effectively ask this Court to step into the district court's shoes and reweigh the equitable factors and other relevant considerations for the purpose of ordering petitioners' desired result: the ability to distribute RRA before APHIS completes an EIS. This Court should not substitute its foot for the Chancellor's. It is simply not the province of an appellate court to engage in such second-guessing of equitable decisions that are properly committed to the discretion of the district court. But even if this Court were inclined to conduct such an intensely fact-bound analysis, the law and the evidence amply support the district court's decision to impose – and the court of the appeals' decision to affirm – the existing injunction.

C. The District Court's Refusal To Impose APHIS's Conditions Was Not An Abuse Of Discretion And Is Justified By Controlling Regulatory Authority

Petitioners also insist that this Court must direct the entry of a more "tailored" injunction. U.S. Br. 29-38; Pet. Br. 25, 47-49. But not just *any* injunction will do – petitioners ask the Court to remand with instructions to enter *APHIS's* proposed judgment. Even if this Court were inclined to reweigh the evidence and assess the merits of that proposal, it should not accede to this particular request. The district court was well within its discretion to decline to impose APHIS's proposed measures, and, in any event, controlling CEQ regulations would have precluded the district court from adopting them.

1. The district court was not required to defer to APHIS's proposed judgment

In arguing that the district court was obligated to enter more limited injunctive relief, the federal respondents and petitioners maintain that Judge Breyer should have deferred to *APHIS* on the scope of the remedy. Pet. Br. 23, 33; U.S. Br. 32-38. That argument, however, improperly equates the standards of judicial review that apply to (a) record-based agency decision-making and (b) an agency's position in civil litigation regarding appropriate redress of its own statutory violation. The former, of course, is entitled to judicial deference. But that standard of review is premised on the notion that, because the agency has followed certain prescribed administrative procedures – including those designed to allow interested parties to comment upon and inform its final decision – the agency is best poised to make the ex-

pert judgment in question. See *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43-51 (1983); *Baltimore Gas & Elec. Co.* v. *NRDC*, 462 U.S. 87, 103 (1983). By contrast, no such deference is owed to agency positions adopted in the course of litigation proceedings. *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 419-20 (1971) ("'post hoc' rationalizations" in "litigation affidavits" are "an inadequate basis for review" and "clearly do not constitute the 'whole record' compiled by the agency"); cf. *State Farm*, 463 U.S. at 50 ("[C]ourts may not accept * * * counsel's *post hoc* rationalizations for agency action."); *Burlington Truck Lines* v. *United States*, 371 U.S. 156, 168 (1962) (same).

In this case, the question is *not* whether the court should have deferred to an agency decision promulgated under the APA's rulemaking procedures. Rather, the agency's position here was adopted in litigation. Moreover, APHIS advanced claims about the environmental impact of its proposal immediately after the district court had concluded that the agency had failed adequately to consider those very same impacts. Indeed, APHIS submitted its proposed judgment just *weeks* after insisting that a proper study of the environmental effects of RRA *would take years*, JA 254, implausibly asserting that its new proposal reflected the consideration necessary to mitigate any harms that might arise from continued – and dramatically increased – use of RRA, JA 362-63. Then, to support that position, it offered just *two* declarations from the head of the program responsible for making deregulation decisions. JA 345-63, 436-45. Not surprisingly, the district court viewed

APHIS's assurances with skepticism and was "not persuaded." Pet.App.67a.

Such abbreviated analysis is miles distant from the detailed findings that typically support agency rulemaking. And that is particularly problematic here, given that APHIS has never before conducted an EIS on a genetically modified product and has been found to have violated NEPA multiple times in connection with its oversight of genetically engineered crops. *Int'l Center for Tech. Assessment* v. *Johanns*, 473 F. Supp. 2d 9, 28-30 (D.D.C. 2007); *Center for Food Safety* v. *Johanns*, 451 F. Supp. 2d 1165, 1183-86 (D. Haw. 2006); *Center for Food Safety* v. *Vilsack*, 2009 WL 3047227, *7-9 (N.D. Cal. Sept. 21, 2009). Under these circumstances, the district court had no obligation to give APHIS's proposal the same deference that would have been owed a record-based decision.

2. Imposition of APHIS's proposed judgment would have violated controlling CEQ regulations

As federal respondents recognize, the scope of an injunction issued to redress a NEPA violation should account for the CEQ regulations that expressly limit the actions available to an agency during the NEPA process. U.S. Br. 31; see also *Marsh* v. *Oregon Nat'l Res. Council*, 490 U.S. 360, 372 (1989) (CEQ regulations "are entitled to substantial deference"); *Andrus* v. *Sierra Club*, 442 U.S. 347, 358 (1979) (same). Those regulations provide, in relevant part, that during the preparation of an EIS, "no action concerning the [agency's] proposal shall be taken which would * * * [h]ave an adverse environmental impact" or

"[l]imit the choice of reasonable alternatives." 40 C.F.R. § 1506.1(a).

The federal respondents suggest that this provision poses no bar to adoption of APHIS's proposed injunction, because only those agency actions that "*materially* harm the environment" are prohibited pending the EIS, and, here, no "material" harms would have occurred had APHIS's proposed conditions been adopted. U.S. Br. 31 (emphasis added). That is wrong for two reasons.

First, the regulation expressly forbids "adverse environmental impact[s]," not just "material harm[s]." Nor can an implied materiality requirement be read into Section 1506.1(a). Elsewhere in the regulations, CEQ is explicit when it intends to limit certain requirements to those items that are "material." See 40 C.F.R. § 1504.3(c)(2)(i) (a referral to the Council shall "[i]dentify any material facts in controversy"). The regulations are also replete with other qualifying words, such as "significant," "major," and "substantial," which direct administrators to focus their attention on particular types of information, impacts, or activities. *E.g.*, *id.* §§ 1500.1(b), 1501.1(d), 1501.6(b)(5), 1501.7, 1502.2(b), 1502.9(a), 1502.9(c)(1), 1502.12, 1502.17, 1502.22, 1505.1(b), 1506.6(c)(1), 1508.17, 1508.18. Had CEQ intended section 1506.1(a) to contain a materiality requirement, as many other provisions do, it would have used language to that effect. Instead, that provision establishes a blanket rule that, until a required EIS is completed, "*no action* concerning the proposal shall be taken which would * * * [h]ave an adverse envi-

ronmental impact * * *." *Id.* § 1506.1(a) (emphasis added).

Second, the argument that environmental effects under the APHIS injunction would have been immaterial is merely an effort to relitigate the district court's summary judgment holding that an EIS was required, precisely for the reason that deregulation would "significantly" affect the environment. 42 U.S.C. § 4332(2)(C). The APHIS injunction mirrored the contractual requirements that would have governed RRA planting under deregulation; the unappealed judgment that such RRA distribution would "significantly" affect the environment forecloses the government's contention that the APHIS injunction would permit only immaterial effects. Therefore, in this context, the CEQ regulation operates as an independent reason why APHIS's proposal should not have been implemented, and the district court correctly declined to do so.

D. If This Court Concludes That The Lower Courts Applied An Incorrect Legal Standard, It Should Remand With Instructions To Reconsider The Injunction Under The Appropriate Standard

For the reasons set forth above, petitioners' request that this Court remand "with instructions to vacate the district court's injunction and enter APHIS's proposed remedy in its place," Pet. Br. 57, countermands centuries of precedent conferring equitable discretion upon district courts and is entirely unjustified on this record. Moreover, petitioners' contention that the lower courts "disregarded this Court's teachings," Pet. Br. 4, *itself* disregards the lower courts' opinions, as well as the substantial evi-

dence supporting their decisions. If, however, this Court determines that the courts below did err in applying the legal standards for injunctive relief, the appropriate disposition would be to remand with instructions that the Ninth Circuit reconsider whether, under the correct legal standards, the district court abused its discretion in granting the injunction – not simply, as petitioners suggest, to remand with instructions to order the entry of petitioners' preferred remedy.

III. THE COURT OF APPEALS CORRECTLY HELD THAT THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION BY DECLINING TO CONDUCT TRIAL-TYPE PROCEEDINGS

On two separate occasions, the district court invited the parties to submit "whatever additional evidence [you] wish to provide," Pet.App.58a-59a; JA 551, and in response the parties submitted hundreds of pages of evidence, including declarations, counter-declarations, and rebuttal materials. In this setting, and on this record, the Solicitor General's conclusion is plainly correct: "[T]he district court did not err in declining to conduct a trial-type hearing." U.S. Br. 39.

A. District Courts Enjoy Broad Discretion In Conducting Injunction Hearings, And There Is No General Right To Trial-Type Procedures

Just as a district court has "substantial discretion to determine whether an injunction should issue," *Huntington* v. *Marsh*, 884 F.2d 648, 653 (2d Cir.

1989), *cert. denied*, 494 U.S. 1004 (1990), so too does it have wide-ranging discretion over the form and content of injunction hearings. *Winter*, 129 S. Ct. at 371-73, 376-78 (considering the proper scope of injunctive relief based upon written submissions); *Califano* v. *Yamasaki*, 442 U.S. 682, 696 (1979) (fact disputes may be resolved on written submissions); see also U.S. Br. 40 n.12 (noting that "courts of appeals routinely dispose of requests for stays in immigration cases based on written submissions, without holding an evidentiary hearing"). Although the nonmoving party must be granted "notice and an opportunity to present its opposition," *Four Seasons Hotels & Resorts, B.V.* v. *Consorcio Barr, S.A.*, 320 F.3d 1205, 1210 (11th Cir. 2003); see *Mathews* v. *Eldridge*, 424 U.S. 319, 348 (1976), the content of such "notice and opportunity" rests with the judge's discretion, *Armstrong* v. *Manzo*, 380 U.S. 545, 552 (1965) (due process demands an opportunity to be heard "at a meaningful time and in a meaningful manner"). And when there is sufficient evidence before the court to render a just and equitable determination on the written record, courts plainly are not required to order an evidentiary hearing. *Mathews*, 424 U.S. at 348 (live witness testimony with cross examination is "neither a required, nor even the most effective, method of decisionmaking"); see, *e.g.*, *FDIC* v. *Morley*, 915 F.2d 1517, 1522 (11th Cir. 1990) ("Parties entitled to such process cannot * * * choose the precise process they desire. * * * Procedures providing less than a full evidentiary hearing have often satisfied due process.").

As the federal respondents correctly point out, trial-type hearings ordinarily are inappropriate in

APA proceedings. U.S. Br. 39-42. "The APA provides for an agency hearing with presentation of live testimony in rulemaking or adjudicatory proceedings *only when required by another statute*," U.S. Br. 40 (emphasis added), and the PPA contains no such requirement, *ibid.* And trial-type proceedings are particularly ill-suited where, as here, the findings in question are prospective or predictive in nature (as with legislative or regulatory determinations), and where the district court's decision is likely to hinge on scientific data rather than determinations about the credibility of fact witnesses. *Id.* at 41. In this setting, a right to present and cross-examine witnesses would not enhance the quality of judicial decisionmaking; it would impose substantial new burdens on the crowded calendars of district courts and on governmental officials. See U.S. Br. 42 n.15; *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951).[22]

Nor is it true, as petitioners contend, that "ancient" principles of equity jurisdiction establish a litigant's right to present live testimony and cross examination. To the contrary, at equity, "almost all testimony [was] positively required * * * to be by written deposition; the admission of viva voce evidence at the hearing being limited to a very few cases, such as proving a deed or a voucher referred to in the case." JOSEPH STORY, COMMENTARIES ON EQUITY JURISPRUDENCE 855 (13th ed. 1988); 3 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS

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[22] These costs are especially unwarranted in the NEPA context, where trial-type proceedings might result in findings that bind the agency in its EIS process or, at a minimum, prejudge the objectivity of that process. See 40 C.F.R. § 1506.1(a).

OF ENGLAND 438 (1768) (in equity courts, trial is taken "by interrogatories administered to the witnesses, upon which their depositions are taken in writing, wherever they happen to reside"). The rules in legal proceedings were different. "At law the testimony is taken *viva voce*, and publicly at the trial of the cause; in equity, according to the ancient practice, the evidence was elicited by interrogatories and cross-interrogatories." GEO. TUCKER BISPHAM, THE PRINCIPLES OF EQUITY: A TREATISE ON THE SYSTEM OF JUSTICE ADMINISTERED IN COURTS OF CHANCERY 17 (10th ed. 1923); accord JOHN ADAMS, JUN., ESQ., THE DOCTRINE OF EQUITY 716 (1873) ("The manner of taking evidence is different in equity and at law. It is taken at law *viva voca*, and publicly; in equity it is written and secret."); Daniel D. Blinka, *Jefferson and Juries: The Problem of Law, Reason, and Politics in the New Republic*, 47 AM. J. LEGAL HIST. 35, 83 (2005) (same); Stephen N. Subrin, *How Equity Conquered Common Law: The Federal Rules of Civil Procedure in Historical Perspective*, 135 U. PA. L. REV. 909, 919 (1987) (same); Fleming James, Jr., *Right to a Jury Trial in Civil Actions*, 72 YALE L.J. 655, 661-62 (1963) (same); HENRY L. MCCLINTOCK, HANDBOOK OF THE PRINCIPLES OF EQUITY 29 (2d ed. 1948) (same).[23]

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[23] See also, *e.g.*, *Lee* v. *State Bank & Trust Co.*, 38 F 2d 45, 49 (2d Cir. 1930) ("Originally, in equity, no oral evidence was taken at the hearing, but testimony was taken by deposition in answer to formal written interrogatories."); *Continental Trust Co of N Y* v. *Toledo, St. L. & K.C.R. Co.*, 99 F. 177, 179 (N D. Ohio Cir. 1900) (same); *Robinson* v *Bailey*, 26 F. 219, 221 (N.D. Iowa Cir. 1885) (same); *Walker* v. *Parker*, 29 F. Cas. 43, 44 (C.C. D.C. 1840) (same).

Testimony in open court was not introduced with any rigor in equity trials until 1848, with the merger of law and equity under the Field Code. Subrin, 135 U. PA. L. REV. at 936-38.[24] And it was only in the 20th Century that Rule 46 of the Equity Rules, the "most radical of all changes in the new rules," provided for the oral testimony of witnesses. Wallace R. Lane, *One Year Under the New Federal Equity Rules*, 27 HARV. L. REV. 629, 639-40 (1914). But even after this change, courts continued to receive evidence in writing. *Ibid.*

The cases petitioners cite (Br. 53-57) are not to the contrary. In *Professional Plan Examiners of N.J.* v. *Lefante*, 750 F.2d 282 (3d Cir. 1984), for example, the district court had enjoined an agency from enforcing the New Jersey Uniform Construction Code Act for a period of more than four years without holding *any* hearings and without making *any* findings of fact or conclusions of law. *Id.* at 288-89. The Third Circuit faulted the district court's *failure to make findings*, not the lack of a hearing, and noted that a "finding of irreparable harm, supported as it is by the affidavits,

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[24] As petitioners observe (Br. 51-52), the Judiciary Act of 1789 merged the modes of proof in federal cases. *Lee*, 38 F.2d at 49. This merger was short-lived, however. The Act of 1802 reinstated equity procedures, providing that "in all suits in equity the court might, in its discretion, upon the request of either party, order evidence to be taken by [written] deposition." *Ibid.* The first Equity Rules, adopted in 1822, maintained "the practice which had grown up by that time of taking testimony by deposition," as did the Equity Rules of 1842. *Ibid.* Throughout the first half of the 19th century, "oral testimony in court was allowable only when the judge in his discretion deemed it advisable." *Ibid.*

would suffice." *Id.* at 289. In *Four Seasons Hotels & Resorts*, the Eleventh Circuit took issue with the way the district court had conducted a hearing because evidence was presented by only one side, thereby depriving appellants of "a fair and meaningful opportunity to oppose appellees' motion." 320 F.3d at 1211. And in *In re Rationis Enterprises., Inc. of Panama*, 261 F.3d 264 (2d. Cir. 2001), the district court had made *no findings* with regard to minimum contacts despite the assertion of a jurisdictional defense. *Id.* at 269.

This case is also a far cry from the *Microsoft* case on which petitioners rely. See *United States* v. *Microsoft*, 253 F.3d 34 (D.C. Cir. 2001). The defendant in *Microsoft* was not given "an opportunity to present its opposition." *Four Seasons Hotels & Resorts*, 320 F.3d at 1210. The judge in *Microsoft* considered the evidence submitted by plaintiffs but refused to give the same consideration to Microsoft, which was able to submit only a summary response to plaintiffs' proposed judgment. 253 F.3d at 103. And the proposed relief in *Microsoft* was the permanent dismemberment of the company, *id.* at 98 – a remedy vastly different in scope and impact from the temporary bar on the unpermitted sale of RRA, designed to maintain the status quo. Neither *Microsoft* nor the other cases cited by petitioners support the proposition that parties have a right to present and cross-examine live witnesses in injunction proceedings.[25]

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[25] Moreover, as the court of appeals explained, because the temporal scope of this injunction is quite limited, the inquiry here parallels most closely that of a preliminary injunction,

B. The Ninth Circuit Correctly Ruled That The District Court Did Not Abuse Its Discretion In Denying Intervenors' Request For Trial-Type Proceedings

Before issuing the permanent injunction, the district court held a hearing on the summary judgment motion, followed by two lengthy hearings on the injunction. See JA 245-55, 412-419, 548-61. The district court considered live testimony (including testimony by the president of FGI), JA 552-54, and offered to "listen to anybody who's – you know, anybody that you suggest that I should hear on the subject." JA 551. The district court later repeated its invitation to consider any evidence the parties wished to submit. Pet.App.58a-59a. In the end, the district court concluded that there simply was no dispute regarding *material* facts – *i.e.*, facts sufficient to overturn the court's conclusion that irreparable harm was "sufficiently likely." Pet.App.13a; see *Amoco*, 480 U.S. at 545.

Significantly, petitioners did not dispute the evidence of actual contamination on which the judge relied, nor did they dispute that the genetic contamination occurred under planting conditions equivalent to those advocated by petitioners and APHIS. Likewise, there were no disputes over the NEPA violation, the government's failure to do the requisite analysis, the prospect of cross-pollination by bees over distances of several miles, the insufficiency of the isolation distances proposed by APHIS in curbing genetic contamination, the duplication of APHIS's

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where courts need not conduct formal evidentiary hearings at all, much less permit trial-type procedures. See Pet.App.18a.

proposed conditions with conditions already imposed by contract (but ineffective in preventing past contamination), or the acknowledged lack of agency resources to enforce any remedial measures. See pages 9-10, *supra*. Those concessions, coupled with the various submissions and counter-submissions of the parties, were more than sufficient to sustain the district court's conclusion that the injunction was warranted.[26]

C. If This Court Concludes That The District Court Had A Duty To Permit Trial-Type Proceedings, It Should Remand For Such A Hearing

Petitioners ask this Court to hold that "*no injunctive relief* may be entered without a hearing," Pet. Br. 53, but they simultaneously seek entry of the injunc-

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[26] Petitioners fault the district court for permitting hearsay evidence to affect its judgment, Pet. Br. 54 n.17, a complaint they raised to the court of appeals only in passing. It is questionable whether the Federal Rules of Evidence even apply in this type of proceeding, see *Heideman* v. *South Salt Lake City*, 348 F.3d 1182, 1188 (10th Cir. 2003), and to the extent declarations submitted by respondents properly are characterized as hearsay, so too are the declarations submitted by petitioners. Even assuming the applicability of the Federal Rules of Evidence, however, the district court considered sufficient non-hearsay evidence, including admissions by petitioners' representatives that instances of contamination had occurred. *E.g.*, Pet.App.404a-409a, JA 1009; see Fed. R. Evid. 801(d)(2). In any event, a district court has leeway to consider otherwise hearsay materials in fashioning temporary equitable relief. See, *e.g.*, *Sierra Club, Lone Star Chapter* v. *FDIC*, 992 F.2d 545, 551 (5th Cir. 1993) (courts at preliminary injunction stage "may rely on otherwise inadmissible evidence, including hearsay"); *Asseo* v. *Pan Am. Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986) ("Affidavits and other hearsay materials are often received in preliminary injunction proceedings.").

tion they prefer without any further proceedings, Pet. Br. 50. Both propositions *cannot* be right. If petitioners have a right to present live testimony and conduct cross-examination concerning material facts that are in dispute, then surely respondents have the same right. For the reasons previously explained, petitioners have no such right. But if the Court rules to the contrary, it should remand for an appropriate hearing, rather than simply enter the injunction petitioners prefer.

CONCLUSION

For the foregoing reasons, the Court should dismiss this case because petitioners lack standing or dismiss the petition as improvidently granted. If the Court proceeds to the merits, the judgment of the court of appeals should be affirmed.

Respectfully submitted.

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MARCH 2010

REPLY BRIEF

No. 09-475

In the Supreme Court of the United States

MONSANTO COMPANY, ET AL., PETITIONERS

v

GEERTSON SEED FARMS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

REPLY BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS

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No. 09-475

MONSANTO COMPANY, ET AL., PETITIONERS

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ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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REPLY BRIEF FOR THE FEDERAL RESPONDENTS SUPPORTING PETITIONERS

As the government's opening brief explains, the district court erred in fashioning the permanent injunction in this case. Even when a federal agency is found to have violated the National Environmental Policy Act of 1969 (NEPA), 42 U S C 4321 *et seq.*, an injunction is appropriate only to the extent that the plaintiff would otherwise suffer irreparable harm See Gov't Br. 18-22. In this case, the Animal and Plant Health Inspection Service (APHIS) identified various protective measures that, taken together, would have prevented such injury from occurring while APHIS was preparing an environmental impact statement (EIS). The district court nevertheless enjoined all new planting of Roundup Ready Alfalfa (RRA) until the EIS is completed, without meaningfully considering whether that broad relief was nec-

essary to prevent irreparable injury to respondents or whether APHIS's proposed protective measures would have sufficed. The district court erred in refusing to defer to APHIS's scientific expertise, and the court of appeals likewise erred in upholding the district court's overly broad injunction.

I. PETITIONERS HAVE STANDING TO CHALLENGE THE DISTRICT COURT'S INJUNCTION

Respondents argue (Br. 17, 19-24) for the first time that petitioners lack standing to challenge the district court's injunction because petitioners did not appeal the portion of the district court's order vacating APHIS's decision to deregulate RRA. Respondents contend that, because vacatur of the deregulation decision would independently prohibit any new sale or distribution of RRA, the injunction has no practical effect on petitioners. Respondents are mistaken.

A. Respondents contend that, because the district court's judgment vacated APHIS's June 14, 2005, deregulation decision, see Pet. App. 108a, all new sale or distribution of RRA would be unlawful (until APHIS completes its EIS) even if no injunction had been entered. As respondents acknowledge (Br 20 n.11), however, the same judgment expressly *permitted* the harvesting and distribution of already-planted RRA subject to certain conditions intended "to minimize the risk of gene flow from the already-planted genetically engineered alfalfa to organic and conventional alfalfa." Pet. App. 76a-77a; *id* at 109a-110a. If, as respondents contend (Br 20), the district court's vacatur of the deregulation decision "restored RRA to its status as a regulated article, the distribution of which is unlawful under the PPA and APHIS regulations," then the distribution of RRA that

is authorized in the same judgment would likewise be illegal. There is no sound reason to construe the district court's judgment as mandating that self-defeating result. Cf. *Western Air Lines, Inc.* v. *Board of Equalization*, 480 U S 123, 133 (1987) (noting, in the statutory interpretation context, that "illogical results" resulting from a proffered interpretation "argue strongly against the conclusion that Congress intended" such a meaning). Rather, the provisions of the judgment are best harmonized by construing it to nullify APHIS's deregulation decision except to the extent that the judgment permits the distribution and sale of RRA grown and harvested pursuant to the conditions enumerated by the district court.

That understanding of the district court's judgment, and of the scope of the controversy that the parties presented to the court of appeals, is reinforced by the events that preceded the judgment. In response to the district court's request, the government submitted a proposed judgment stating that APHIS's deregulation decision "is hereby vacated and replaced by the terms of this judgment " Pet. App. 184a The government's proposed judgment would have permitted the continued planting of RRA subject to enumerated protective measures. *Id.* at 185a-187a. That proposed judgment, under which the specified restrictions would have "replaced" APHIS's deregulation decision, plainly contemplated that continued planting, harvesting, and sale of RRA would be lawful so long as those restrictions were obeyed, notwithstanding the vacatur of the deregulation decision.

APHIS's subsequent statements that it did not challenge the district court's vacatur of the deregulation order simply reflect the government's decision not to

contest on appeal the district court's requirement that APHIS prepare an EIS. Similarly, the government did not seek on appeal to reinstate the complete deregulation of RRA before completing the EIS But the government and petitioners did appeal the district court's judgment, and the thrust of the appeal was that the district court should have adopted the government's proposed judgment instead. Because that alternative judgment would have given petitioners significantly greater opportunities to sell RRA than did the district court's blanket prohibition of new planting during APHIS's preparation of an EIS, petitioners have been injured by the district court's choice of remedies and by the court of appeals' decision affirming that choice.

B. Respondents' own litigation conduct assumes that the district court's entry of a broad injunction, rather than the more narrowly-tailored order proposed by the government, would have meaningful practical consequences. If the court's vacatur of APHIS's deregulation decision "independently prevents petitioners' sale or distribution of RRA," as respondents contend (Br 17, 19-22), there would have been no need for respondents to seek an injunction. Respondents sought such relief, however, and they have vigorously defended the injunction that the district court entered. Indeed, respondents' claim (*id.* at 35-43) that the broad injunction entered by the district court was necessary to prevent irreparable harm to themselves is premised on the understanding that increased planting of RRA would have occurred if the court had instead entered the order that the government proposed That argument cannot be squared with respondents' belated contention that the injunction is superfluous

C. Respondents' standing argument is also at odds with decisions of this Court—such as *Weinberger* v *Romero-Barcelo*, 456 U.S. 305 (1982)—dealing with the prerequisites to entry of injunctive relief. In *Romero-Barcelo*, the district court found that the United States Navy was violating the Federal Water Pollution Control Act (FWPCA), 33 U.S.C. 1251 *et seq*, by discharging pollutants (munitions) into the waters surrounding Vieques, Puerto Rico during training operations without first obtaining a permit. 456 U.S. at 307-308. Although the district court declared the Navy's actions to be in violation of the FWPCA and ordered the Navy to take the steps necessary to comply with that law, it declined to issue an injunction prohibiting the Navy from continuing its training operations pending procurement of the necessary permit. *Id* at 309-310. The court of appeals vacated the district court's order and remanded with instructions to enter such an injunction, *id* at 310-311; but this Court reversed the court of appeals. The Court observed that "a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law." *Id.* at 313 The Court's opinion (see *id.* at 311-320) made clear both that the decision whether to grant an injunction is discretionary and that the decision has important practical consequences. Respondents' standing argument, which treats a district court injunction as adding nothing of substance to a pre-existing statutory prohibition, cannot be reconciled with that analysis.

II. THE DISTRICT COURT ERRED IN ENTERING AN OVERLY BROAD PERMANENT INJUNCTION

The district court held that APHIS had violated NEPA by failing adequately to assess whether deregula-

tion of RRA would "significantly affect[] the quality of the human environment," 42 U.S C. 4322(2)(C), through allowing RRA genetic material to cross-pollinate with non-RRA alfalfa. Pet. App. 35a-45a.[1] In entering a broad permanent injunction against new planting of RRA, however, the court failed meaningfully to consider whether the interim protective measures proposed by the government would suffice to prevent irreparable harm to respondents. Respondents' attempts to defend the purported legal and factual bases for the district court's broad injunction are unavailing.

A. The district court acknowledged that, in NEPA cases, a plaintiff's request for an injunction "requir[es] the court to engage in the traditional balance of harms analysis." Pet. App. 65a (quoting *Forest Conservation Council* v *United States Forest Serv*, 66 F.3d 1489, 1496 (9th Cir. 1995)) Respondents contend (Br 30-31) that the district court then faithfully applied the factors in that analysis to the record in this case. In fact, however, the court specifically declined to assess whether the protective measures proposed by APHIS would adequately safeguard against cross-pollination. The court stated that it could not appropriately conduct such an inquiry because "[t]o make the findings requested by [the government] would require [the district court] to engage in precisely the same inquiry it concluded APHIS failed to do and must do in an EIS." Pet. App. 68a; see *id* at 67a-69a; see also *id* at 192a ("I am not

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[1] The district court also determined that APHIS had failed to consider whether the deregulation of RRA would lead to the development of glyphosate-resistant weeds Pet App 45a-47a But in rejecting APHIS's proposed interim measures in favor of broader injunctive relief, the court focused on the potential for cross-pollination with non-RRA alfalfa *Id* at 67a-71a

going to get into the isolation distances."), *id.* at 417a ("I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it.").

That analysis is flawed in three fundamental respects. First, the court erred in equating the scientific inquiry involved in APHIS's preparation of an EIS with the inquiry needed to determine the proper scope of injunctive relief. Whereas the final EIS will analyze the potential environmental effects that complete deregulation of RRA would entail, the question for the district court at the remedial phase of this case was whether continued planting and harvesting of RRA subject to APHIS's proposed protective measures would likely cause irreparable harm to respondents during the limited interval in which the EIS is being prepared. See pp. 8-13, *infra*, cf. *National Audubon Soc'y* v. *Department of the Navy*, 422 F.3d 174, 201 (4th Cir. 2005) (A "NEPA injunction predicated on preventing environmental harm can be overbroad if it restricts nonharmful actions—even ones that are precursors to other actions that are potentially harmful."). Second, even if the overlap between the two inquiries were more substantial, the burden would still have been on respondents to demonstrate that the more narrowly-tailored injunction proposed by APHIS would not protect them from irreparable harm. Cf. *Amoco Prod. Co.* v. *Village of Gambell*, 480 U.S. 531, 544-545 (1987) (rejecting the court of appeals' conclusion in that case that "[i]rreparable damage is *presumed* when an agency fails to evaluate thoroughly the environmental impact of a proposed action," and stating that such a presumption "is contrary to traditional equitable principles" and is not necessary to "fully protect[]" the environment) (first set of brackets in orig-

inal). Third, the district court should have treated its own acknowledged lack of specialized expertise in environmental analysis as a reason to defer to the responsible federal agency, not as a ground for issuing a broader injunction. See pp. 13-17, *infra*.

B. If the district court had found that APHIS's proposed protective measures were insufficient to prevent irreparable harm to respondents, and that a broad injunction prohibiting the further planting of RRA was necessary to prevent such injury, that finding would have been clearly erroneous The evidence before the court established that cross-pollination between RRA and conventional or organic alfalfa would have been unlikely if the court had issued the more limited injunction that the government proposed.

In explaining its decision to enter a broad permanent injunction against new planting of RRA, the district court stated that "contamination of organic and conventional alfalfa crops with the genetically engineered gene ha[d] occurred" in the past. Pet. App 71a. Respondents defend the court's remedial action on the same basis. See Br 7-8, 36. But the *only* evidence of actual gene transfer found in the record involved cross-pollination of conventional or organic alfalfa plants grown to produce seed. Those plants represent a tiny percentage of the alfalfa market. More than 99 5% of the alfalfa grown in this country is grown for hay rather than for seed. Pet. App 321a. In order for genetic material to transfer from an RRA hay field to a hay field of conventional or organic alfalfa, a series of independently unlikely events would have to occur seriatim. See Gov't Br. 25-26; Pet Br. 43-45

Thus, as petitioners explained in the district court, Pet. App. 278a, 379a, the likelihood of hay-to-hay cross-

pollination is essentially zero. Indeed, respondents do not contend either that such cross-pollination is likely to occur or that it has ever previously occurred At the very least, the injunction is thus substantially overbroad in preventing any planting and harvesting of RRA grown for hay, and it is out of step with this Court's instruction that a district court entering an injunction must "mould each decree to the necessities of the particular case." *Romero-Barcelo*, 456 U.S. at 312 (quoting *Hecht Co* v. *Bowles*, 321 U S 321, 329 (1944)).

Although the risk of cross-pollination is greater with respect to the 0.5% of alfalfa plants that are grown for seed, the measures the government urged the district court to incorporate into an injunction would have responded to that heightened risk. The Association of Official Seed Certifying Agencies permits a maximum percentage of 1% of seeds of other varieties in a batch of certified alfalfa seeds. Certified seed is the highest quality seed that farmers plant to raise alfalfa for hay Pet App. 163a. The isolation distances APHIS proposed between RRA fields grown for seed and non-RRA alfalfa fields grown for seed were designed to limit cross-pollination to 0.1%. *Id* at 162a-163a. APHIS's proposed isolation distances were thus intended to limit cross-pollination to a level that is ten times more stringent than the industry standard (*i e* , one in 1000 seeds may be of a different variety rather than one in 100).

The district court credited respondents' evidence that some fields of conventional or organic alfalfa grown for seed had been cross-pollinated by RRA. Pet. App. 71a. But respondents are incorrect in asserting (Br. 44) that the conditions under which RRA was grown during the more than 20 months after APHIS's deregulation decision are "virtually identical to those proposed by

APHIS" in the remedial phase of this case. The contracts between petitioners and RRA growers required that RRA hay fields be harvested at or before ten percent bloom in areas in which non-RRA alfalfa plants were grown for seed. J.A. 260. The agreements also required that RRA fields grown for seed be separated from non-RRA alfalfa seed fields by 900 feet when leaf cutter bees are used for pollination and by three miles when honey bees are used. *Id* at 280.

The protective measures included in the government's proposed injunction would have been more stringent in a number of respects. First, they would have prohibited the introduction of pollinators in RRA hay fields. Pet. App 185a. Second, whereas petitioners did not require any isolation distances between RRA hay fields and non-RRA alfalfa fields used for certified seed production, the government's proposed injunction would have imposed harvest restrictions on hay fields located within 500 feet of any alfalfa fields used for certified or common seed. *Id.* at 185a-186a; J.A. 439.[2]

Third, APHIS's protective measures would have increased the required isolation distances between RRA fields grown for seed and non-RRA alfalfa seed fields from 900 feet to 1500 feet when leaf cutter bees are used as pollinators. Pet. App. 186a. Fourth, the proposed injunction would have introduced a requirement that all equipment that comes into contact with RRA be cleaned

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[2] APHIS would have required that growers of RRA identify and keep records of all alfalfa crops grown within 500 feet of their fields Pet App 185a Under the government's proposed injunction, any RRA field within 165 feet of a certified or common alfalfa seed field would have had to be harvested before flowering, and any RRA field between 165-500 feet of a seed field would have had to be harvested at or before ten percent bloom *Id* at 186a

pursuant to approved techniques before leaving the farm on which the RRA is grown. *Id* at 186a-187a. Finally, APHIS would have prohibited the use of RRA for livestock grazing purposes or in mixed-grass pastures, *id* at 187a, both of which were permitted under petitioners' contracts.[3]

Respondents fail to refute APHIS's conclusion that the stringent protective measures set forth in the government's proposed injunction would have significantly diminished, if not eliminated, the risk of cross-pollination even between seed plants. More importantly, the district court refused to consider whether the measures APHIS proposed would have mitigated the potential for any irreparable harm the district court thought possible Cf. *Winter* v. *NRDC*, 129 S Ct 365, 376 (2008) (characterizing as "significant" the district court's failure, after the government challenged only two of the six restrictions initially imposed by the court, to determine whether the four unchallenged restrictions would be sufficient to prevent irreparable harm).

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[3] APHIS carefully designed those measures to prevent cross-pollination in the small segment of the alfalfa market grown for seed from rising above the levels permitted by industry standards Respondents apparently are not satisfied with the industry standards, preferring instead to operate in an alfalfa market with zero tolerance for genetically modified traits See Br 40 But there is no sound basis for concluding that the district court's broad injunction is necessary even for that purpose Ample evidence shows, for example, that alfalfa growers have cooperated to take voluntary steps to bring the risk of cross-pollination down to zero by creating "GE free" zones in which no genetically engineered crops are grown See, *e g* , National Alfalfa & Forage Alliance, *Coexistence for Organic Alfalfa Seed & Hay Markets* 3 (June 2008), National Alfalfa & Forage Alliance, *Coexistence for Alfalfa Seed Export Markets* 2 (June 2008)

Even if some cross-pollination of conventional or organic alfalfa plants by RRA were likely to occur with APHIS's proposed restrictions in place, the evidence before the court established that any such cross-pollination does not constitute irreparable injury. The only evidence of cross-pollination presented to the district court involved a handful of specific alfalfa crops grown for seed. See Resp. Br. 7-8. But the unwanted cross-pollination of a single field or a handful of fields is not irreparable harm—either to the farmer involved or to the environment.

The record evidence demonstrated that the cross-pollination of a conventional or organic alfalfa field by RRA genetic material can be eliminated within one growing cycle. C.A. E R 70-71 (¶ 18), 104; Pet App 397a, 409a-410a. Such a readily eliminated effect is not "irreparable" under any normal understanding of that word. Although the measures necessary to eliminate unwanted cross-pollination entail monetary costs, such compensable economic harm (even if not speculative) is not the type of harm federal injunctions are intended to prevent. See, *e.g.*, *Romero-Barcelo*, 456 U.S. at 312 ("An injunction should issue only where the intervention of a court of equity 'is essential in order effectually to protect property rights against injuries otherwise irremediable '") (quoting *Cavanaugh* v. *Looney*, 248 U.S. 453, 456 (1919)), Gov't Br. 28 (explaining that harm caused by unwanted cross-pollination may be remediable through money damages from the responsible private party). And such potential economic harm is not the sort of environmental harm that is the principal focus of NEPA.

Respondents suggest (Br 31 n.15, 38) that petitioners (and presumably the government) have conceded that respondents satisfied the irreparable-harm stan-

dard for at least some form of injunctive relief. That is incorrect. When the district court granted summary judgment to respondents on their claim that APHIS had violated NEPA by failing to prepare an EIS, the court ordered the parties to "confer and submit a proposed Judgment to the Court." Pet. App. 53a; see *id.* at 54a. In response to that directive, the government proposed an injunction that would have allowed continued planting and harvesting of RRA if done in compliance with specified protective measures devised by APHIS. See *id.* at 184a-187a. Petitioners have indicated (see Br. 25 & n.9) that they do not object to entry of that form of relief.

The parties' litigation conduct narrowed the range of issues that the courts below were required to resolve, but it did not reflect a concession that respondents would suffer irreparable harm in the absence of an injunction. In this respect, this case is analogous to *Winter*, in which the Navy challenged only two of the six restrictions imposed by the district court, see 129 S. Ct. at 373, 376, but did not thereby concede that the other restrictions were proper. The Court in *Winter* squarely rejected the suggestion that either the Navy's prior efforts to mitigate environmental harms potentially caused by its training exercises or the Navy's decision not to challenge four of the six restrictions imposed by the district court was inconsistent with the government's representations as to the disruptive effect of the two challenged restrictions. See *id.* at 380 ("Apparently no good deed goes unpunished.")

C. In determining the appropriate scope of injunctive relief, the district court erred in refusing to defer to APHIS's judgment that the protective measures it proposed were adequate to avoid environmental harm while

an EIS was being prepared. As the government's opening brief explains (Br. 35-38), courts reviewing agency action should defer to the conclusions of agency officials that are based on their particular expertise and on scientific evidence. *E.g.*, *Marsh* v. *Oregon Natural Res. Council*, 490 U.S. 360, 376-377 (1989); *BG&E* v. *NRDC*, 462 U.S. 87, 103 (1983). Respondents argue (Br. 46-47) that deference is inappropriate in this case because the government's judgment about the appropriate scope of an injunction was "adopted in litigation" rather than "record-based agency decision-making." In support of its proposed judgment, however, the government submitted declarations prepared by the responsible APHIS official setting forth his reasons for concluding that the proposed restrictions would prevent cross-pollination between RRA and conventional or organic alfalfa while APHIS was preparing the EIS. See Pet. App. 137a-167a. In reaching that conclusion, the APHIS declarant drew on his own scientific expertise and on the agency's broader experience in administering the PPA, including authorizing and monitoring field trials of RRA during the period before deregulation. See *id.* at 140a-141a.

This Court confronted a closely analogous situation in *Winter*, in which the government submitted declarations of Navy officials that explained why the restrictions imposed by the district court would impede the Navy's training exercises. 129 S. Ct. at 377. The Court held that the district court was required to defer to the expert judgments set forth in those declarations. *Ibid.* The same is true in this case, in which APHIS officials utilized their scientific and professional expertise, and their experience in administering the PPA, including authorizing and monitoring field trials of RRA prior to deregulation, in crafting a remedy that would eliminate

the risk of cross-pollination for over 99% of the alfalfa in this country (*i e*, alfalfa grown for hay) and significantly restrict that risk in the remaining crop. By its own admission (see pp. 6-7, *supra*), the district court was not in a position to make a better scientific assessment of the agricultural principles bearing on its choice of remedy. The district court therefore should have deferred to the judgment of APHIS rather than substituting its own. See *Florida Power & Light Co.* v. *Lorion*, 470 U.S. 729, 744 (1985); *Camp* v. *Pitts*, 411 U.S. 138, 143 (1973) (per curiam); see also 33 Charles Alan Wright & Charles H Koch, Jr., *Federal Practice and Procedure Judicial Review of Administrative Action* § 8313, at 97 (2006) ("Even legislative facts found in adjudication should be left to the agency."); *id* § 8375, at 307.[4]

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[4] Respondents' reliance on decisions holding that courts should not defer to an agency's "*post hoc* rationalizations" of a challenged agency action, Br 47 (quoting *Motor Vehicle Mfrs Ass'n of the United States* v *State Farm Mut Auto Ins Co*, 463 U S 29, 50 (1983)), is similarly misplaced Those decisions caution against reliance on an agency's rationalization in litigation for the agency action being challenged in the case See *Citizens to Preserve Overton Park, Inc* v *Volpe*, 401 U S 402, 419-420 (1971), *Burlington Truck Lines, Inc* v *United States*, 371 U S 156, 168-169 (1962) In this case, however, neither the APHIS declarations nor the government's proposed injunction reflected an effort to defend the agency action under review (*i e*, the deregulation of RRA without preparation of an EIS) The proposed injunction took as a given the district court's prior holding that the deregulation decision violated NEPA, indeed, the government's proposed injunction would have directed APHIS to prepare an EIS See Pet App 184a The agency declarations (which were executed after the district court had granted respondents' motion for summary judgment on the merits of their NEPA claim) likewise did not attempt to defend the prior deregulation decision or to assess the environmental consequences of complete deregulation, but instead explained why APHIS's proposed interim protective measures were sufficient to prevent any likelihood of irreparable

If APHIS had determined at the outset that it would prepare an EIS before deciding whether to deregulate RRA, the PPA would have allowed the agency to devise a set of protective measures that would govern the planting of RRA while the EIS was in preparation. See Gov't Br. 36-37. If the agency had taken that approach and had made a Finding of No Significant Impact (FONSI) with respect to interim planting under those protective measures, and if a plaintiff had challenged the agency's FONSI, the reviewing court would have been required to apply a deferential standard reflecting appropriate respect for the agency's scientific expertise. Under this Court's decision in *Winter*, 129 S Ct. at 377, APHIS's judgment as to the adequacy of specified protective measures should receive comparable deference when expressed in agency declarations rather than a pre-litigation FONSI.

Respondents further suggest (Br. 47) that APHIS's declarations should be viewed with skepticism because the agency submitted those declarations shortly after it informed the court that it would need years to complete the EIS. But that suggestion is based on the erroneous contention (*ibid.*) that the declarations addressed the "very same impacts" that the EIS would analyze. Whereas the EIS would address the potential environmental consequences of complete deregulation of RRA, the declarations address the potential environmental consequences of planting RRA (a) during the limited period pending completion of the EIS and (b) subject to the extensive protective measures reflected in the pro-

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harm while the EIS was being prepared. There is consequently no reason to doubt that the declarant's conclusions as to the adequacy of the proposed restrictions pending preparation of the EIS represented the agency's best expert judgment.

posed judgment. In proposing a tailored injunction, APHIS was exercising its scientific expertise and drawing upon its regulatory experience, not short-circuiting the EIS process

D. Respondents are also incorrect in contending (Br. 48-49) that NEPA regulations promulgated by the Council on Environmental Quality (CEQ) barred the district court from adopting APHIS's proposed protective measures. The CEQ regulations do not require all related agency actions to cease while an EIS is being prepared. Rather, they specify that, during the preparation of an EIS (when one is required), an agency may not take any action in connection with the implicated activity that would "[h]ave an adverse environmental impact" or would "[l]imit the choice of reasonable alternatives " 40 C.F.R. 1506.1(a). In this case, APHIS's proposed injunction would have imposed conditions on the continued planting of RRA that were reasonably designed to prevent cross-pollination between RRA and conventional or organic alfalfa. Continued planting and harvesting of RRA under those protective measures while the EIS was being prepared therefore would not "[h]ave an adverse environmental impact" within the meaning of Section 1506.1(a).

CEQ's "adverse environmental impact" standard is not triggered simply by speculation as to the possibility of interim harm. Nor, contrary to respondents' contention (Br. 49), does it encompass interim actions that are likely to have trivial environmental consequences. An agency is required to prepare an EIS only if the proposed federal action would "significantly affect[] the quality of the human environment," 42 U.S.C 4332(2)(C); a more abbreviated analysis is appropriate if the agency determines that the action's environmental

impact is not "significant." 40 C.F R. 1501.4(e). Under respondents' approach, however, the CEQ regulations would prohibit a federal action having trivial (but non-zero) environmental effects if that action concerns a larger proposed action for which the relevant agency is preparing an EIS. That construction of the CEQ regulations would impose unreasonably severe limits on agency conduct, and it is unnecessary to fulfill NEPA's objectives of informed decisionmaking and public participation. See *Department of Transp.* v. *Public Citizen*, 541 U S 752, 768 (2004); *National Audubon Soc'y*, 422 F.3d at 203 ("CEQ regulations and our own caselaw make clear that agency action prior to completing a sufficient environmental study violates NEPA only when it actually damages the environment or 'limit[s] the choice of reasonable alternatives '") (brackets in original) (quoting 40 C F.R. 1506 1(a)(2)).

Because interim planting under APHIS's proposed conditions would not "[h]ave an adverse environmental impact" within the meaning of Section 1506.1(a), it is permissible under the CEQ regulations as long as it does not limit the agency's choice of reasonable alternatives Respondents do not contend that the planting of RRA subject to APHIS's proposed conditions would have limited the options available to APHIS upon completion of the EIS. And because any cross-pollination that might occur under the conditions APHIS proposed (a remote possibility in any event) could be readily reversed (see p. 12, *supra*), adoption of the government's proposed injunction would have left all reasonable alternatives open to the agency The remedy that APHIS proposed was thus fully consistent with the CEQ regulations, and with NEPA's purpose of "ensur[ing] that important effects will not be overlooked or underestimated

only to be discovered after resources have been committed or the die otherwise cast." *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989)

III. A DISTRICT COURT IS NOT REQUIRED IN EVERY CASE TO HOLD A FULL TRIAL-LIKE HEARING BEFORE ENTERING AN INJUNCTION

Petitioners argue (Br. 50-57) that the district court erred in entering an injunction without first holding a trial-like evidentiary hearing with live-witness testimony and cross-examination. As the government's opening brief explains (at 38), the Court can readily decide this case without determining whether petitioner's contention is correct The disputed question before the district court was whether the protective measures proposed by APHIS were sufficient to prevent a likelihood of irreparable harm to respondents, or whether a broader injunction was needed to accomplish that objective The district court's fundamental error lay in its refusal to decide that question at all, not in its use of deficient fact-finding procedures to resolve it In light of that error, this Court need not determine what procedures the district court should have utilized and what forms of evidence it should have considered in deciding that essential issue.

If the Court does address the question, however, it should hold that a full-blown oral evidentiary hearing is not required in every case in which the propriety of injunctive relief turns in part on the resolution of factual disputes. That is particularly so given the administrative-law context of this case. The type of process required in the administrative context varies with the type of determination an agency is called upon to make, and a trial-like evidentiary hearing "is neither a

required, nor even the most effective, method of decisionmaking in all circumstances." *Mathews* v *Eldridge*, 424 U.S. 319, 348 (1976).

When an agency is called upon to make a predictive judgment about matters not unique to a particular case, it is generally not required to hear live oral testimony or permit cross-examination of witnesses. See *Mobil Oil Exploration & Producing Se., Inc* v. *United Distrib Cos.*, 498 U.S. 211, 228 (1991); *United States* v. *Florida E Coast Ry*, 410 U.S. 224, 239-240 (1973); see also Henry J. Friendly, *Some Kind of Hearing*, 123 U. Pa. L. Rev. 1267, 1302-1303, 1307 (1975) (Friendly). In particular, such a hearing is not mandated when an agency's decision is based on scientific evidence or other judgments predicated on professional expertise. *Matthews*, 424 U.S. at 344-346; Friendly 1284-1285 (noting that, in cases dealing with "recondite scientific or economic subjects[,] * * * the main effect of cross-examination is delay"). Such determinations are legislative or regulatory rather than adjudicative in nature. Thus, if APHIS had proposed to adopt a regulation imposing the same restrictions on RRA planting and harvesting that were contained in the government's proposed injunction, neither regulated parties nor members of the public would have had a right to an oral hearing before the agency to express their views on the proposal See Gov't Br 41-42 & n.14.

There is no sound reason to accord petitioners a greater right to present live testimony or cross-examine witnesses with respect to the district court's choice of an equitable remedy than they would have had in analogous agency proceedings. In the NEPA context, the propriety of equitable relief is likely to turn on the weighing of scientific or economic evidence rather than the credibil-

ity of particular fact witnesses. Indeed, this Court has admonished that courts reviewing agency action should not "probe the mental processes" of the agency's decisionmaker. *United States* v. *Morgan*, 313 U.S. 409, 422 (1941) (citation omitted); see *National Audubon Soc'y*, 422 F.3d at 203 ("[I]nquiries into an agency's subjective intent and the necessity of its substantive decision exceed the permissible scope of judicial review in a NEPA case."). That prohibition is consistent with the general rule that a reviewing court should defer to an agency's resolution of questions within its scientific or technical expertise and may not substitute its own judgment for that of the agency. See pp. 13-17, *supra*. Moreover, the routine use of such testimony risks monopolizing the time of agency officials. *In re United States (Kessler)*, 985 F.2d 510, 512 (11th Cir. 1993) (per curiam)

Petitioners identify no provision of law that requires an opportunity for live testimony and cross-examination as a predicate to entry of an injunction. Even assuming that entry of the injunction in this case "deprived" petitioners of "property" and thus implicated the protections of the Due Process Clause, U.S. Const. Amend. V, the opportunity to present live testimony is not in all circumstances an essential attribute of fair process. To be sure, Federal Rule of Civil Procedure 65 assumes that the district court will conduct a "hearing" before issuing an injunction. But that simply means that a court may not enter an injunction ex parte (cf. Fed. R. Civ P. 65(b)(1), dealing with temporary restraining orders) and that the defendant must be given an adequate opportunity to present evidence and argument. Cf. *Florida E. Coast Ry* , 410 U.S. at 239-242 (statutes requiring Interstate Commerce Commission to conduct a "hearing" as a predicate to ratemaking did not give in-

terested parties a right to present oral testimony or cross-examine witnesses) The Rule does not specify the form in which the court must receive that evidence, and in particular does not demand a full-blown oral evidentiary hearing.[5]

* * * * *

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed, and the case should be remanded with instructions to vacate the permanent injunction entered by the district court.

Respectfully submitted

ELENA KAGAN
Solicitor General

APRIL 2010

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[5] As respondents note (Br 53-55), the early English courts at equity "did not take testimony in open court, but relied on documents " Stephen N Subrin, *How Equity Conquered Common Law The Federal Rules of Civil Procedure in Historical Perspective*, 135 U Pa L Rev 909, 919 (1987) Such courts relied primarily on sworn pleadings and written depositions taken by a court officer in private after receiving written interrogatories rather than on oral testimony taken before the factfinder and subject to cross-examination Fleming James, Jr , *Right to a Jury Trial in Civil Actions*, 72 Yale L J 655, 661-662 (1963), Geo Tucker Bispham, *The Principles of Equity A Treatise on the System of Justice Administered in the Courts of Chancery* 13 (Joseph D McCoy ed , 11th ed 1931), accord Daniel D Blinka, *Jefferson and Juries The Problem of Law, Reason, and Politics in the New Republic*, 47 Am J Legal Hist 35, 83 (2005)

REPLY BRIEF

Supreme Court, U.S.
FILED
APR 20 2010
OFFICE OF THE CLERK

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,
Petitioners,
v.
GEERTSON SEED FARMS, ET AL.,
Respondents.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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ARGUMENT

The Ninth Circuit's decision in this case affirms a nationwide injunction on the use of Roundup Ready alfalfa ("RRA") that is fatally flawed in numerous respects and profoundly out of step with this Court's precedents. Respondents do not seriously defend the fundamental errors of law that drove the Ninth Circuit's decision and occasioned this Court's review. Instead, respondents focus their efforts on avoiding review of the Ninth Circuit's decision altogether and in recharacterizing the Ninth Circuit's ruling. Those efforts should be rejected.

Respondents' standing argument—which they did not make in their brief in opposition to certiorari—is misguided. This Court's decisions endorse the common-sense principle that an injunction imposes a distinct legal injury on those subject to it, thus conferring standing to challenge it. The injunction in this case is no different. And that injunction is part and parcel of the vacatur order on which respondents now focus—and, indeed, is part of the same *judgment* that is on appeal in this case. Pet.App.108a-10a. The injunction defines the scope of the vacatur. That is underscored by the fact that the injunction allows the continued use of RRA planted before March 30, 2007, even though the use of any RRA would be unlawful if the vacatur order had the effect now hypothesized by respondents to avoid review here. Contrary to respondents' view, petitioners' appeal of the judgment validly challenged the scope of the vacatur as well.

Respondents' attempt to avoid scrutiny of the Ninth Circuit's actual approach by recasting the decisions below as routine applications of the familiar four-factor test fares no better. No matter how loudly

respondents proclaim that the lower courts "did not even *suggest*" (Resp.Br.25) that NEPA cases are different, they cannot account for what those courts actually said and did. The district court declined to engage in any serious inquiry into the likelihood of irreparable harm because the court believed that it was not "[its] job" (Pet.App.417a) to undertake such an inquiry in a NEPA case in which the agency was going to conduct an EIS anyway. And in affirming the injunction the Ninth Circuit expressly followed its own prior holdings that courts considering injunctive relief in the NEPA context should avoid "duplicat[ing]" the efforts that an agency may undertake in conducting an EIS and that injunctions are appropriate for NEPA violations except in "unusual" cases. Pet.App.12a, 18a-19a. In other words, just as in *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 393 (2006), it is immaterial whether the courts below correctly "recited the traditional four-factor test," because they rested their decisions on "expansive principles" that would change the ground rules for injunctions in a category of cases—here, NEPA cases.

Finally, respondents' psychological *fear* that RRA will lead to the extinction of all non-RRA alfalfa cannot override the record evidence—and science on which it is based—establishing that this will not happen. As we have explained, the risk of *any* harm from RRA cross-pollination is exceedingly small. Even in the unlikely event that cross-pollination does occur, it will not change the constitution of *any* existing alfalfa plant. Pet.App.147a. The risk is only that a cross-pollinated plant will produce seeds that could grow into RRA plants. But those seeds, if unwanted, can be identified through inexpensive testing and destroyed. The

suggestion that RRA will spread like wildfire and eliminate varieties of conventional alfalfa is entirely unfounded. Pet.App.320a, 385a-87a, 409a-10a.

Once these arguments are put aside, respondents have little to say about the legal issues that are actually presented. For example:

- Respondents do not defend the Ninth Circuit's erroneous view that a court may enjoin the underlying activity when a NEPA violation exists without finding likely irreparable injury because the agency might be analyzing potential environmental harms in its EIS process.
- Respondents do not dispute that the chances of any RRA cross-pollination in alfalfa that is grown for hay—which accounts for 99% of alfalfa acreage—is 400,000-to-one and that there is no record evidence it has ever occurred.
- Respondents do not dispute that, with use of APHIS's proposed isolation distances, material cross-pollination from RRA seed crops is unlikely, and that cross-pollination from RRA seed crops has never resulted in any actual commercial harm or loss of organic certification.
- And respondents do not defend the district court's refusal to consider alternative isolation distances or disavow their prior concession that "five mile" or "several" mile isolation distances would provide a "zero tolerance" approach.

Especially in light of these important omissions, sustaining the injunction at issue would represent a stark departure from the principles that this Court reaffirmed just last Term in *Winter v. NRDC*, 129 S. Ct. 365 (2008). The judgment below should be

reversed, and the case remanded with instructions to enter APHIS's proposed remedy.

I. PETITIONERS HAVE STANDING TO APPEAL THE INJUNCTION

Respondents contend that petitioners, though parties subject to the injunction, have no standing to challenge it. That argument is flawed on several levels.

First, the district court's vacatur order is inextricably tied to the scope of the injunction and, indeed, is part of the same *judgment*. Pet.App.108a-10a. The terms of the injunction modify—and limit—the terms of the vacatur. If the district court had vacated the deregulation order in its entirety, that would have made it unlawful not only to plant new RRA but also to cultivate and sell RRA that had previously been planted. 7 C.F.R. §340.0. But by its terms, the judgment explicitly *allowed* the continued use of "alfalfa planted before March 30, 2007." Pet.App.108a-09a. Thus, the district court's judgment necessarily effects a *partial* deregulation in which the scope of the vacatur is coextensive with, but no broader than, the scope of the injunction. When petitioners appealed the judgment and argued that the injunction was invalid, they therefore appealed and challenged the scope of the vacatur as well.[1]

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[1] The government's interim injunctive measures were expressly framed as a limitation on the scope of the vacatur. *See* Pet.App.184a ("Pursuant to the Order, [APHIS's nonregulation order] is hereby vacated *and replaced by the terms of this judgment*.") (emphasis added). Petitioners have consistently argued that the district court erred in not adopting those measures. And, in response to respondents' contention on appeal that the district court could not adopt the government's proposed measures, petitioners likewise argued both that the district court

Second, even if the judgment had effected a *complete* vacatur, the injunction is broader, and inflicts independent harm on petitioners. The injunction additionally prohibits APHIS from deregulating RRA "even in part" without preparing an EIS (or taking other regulatory action to permit commercial RRA planting). Pet.App.108a; *see* Pet.App.75a. But for this additional component of the injunction, APHIS could have implemented an interim solution allowing continued planting. Pet.App.184a-87a. APHIS's declarations make that crystal clear. Pet.App.158a-67a; *see also* U.S.Br.9-10, 36-37. Whatever else is true about the scope of the vacatur, the district court's preclusion of that additional option caused petitioners an independent and concrete harm.

Third, and in any event, it is black letter law that the entry of an injunction prohibiting the same conduct imposes an independent judicial constraint—and thus inflicts an independent legal injury—that petitioners have standing to challenge on appeal. *See Horne v. Flores*, 129 S. Ct. 2579, 2592 (2009) (named defendant, found liable and enjoined, "[f]or these reasons alone, ... has alleged a sufficiently 'personal stake in the outcome of the controversy' to support standing" to challenge the injunction) (citation omitted); *id.* (citing and quoting with approval *United States v. Sweeney*, 914 F.2d 1260, 1263 (9th Cir. 1990) (rejecting as "frivolous" the argument that a party does not have "standing to object to orders specifically directing it to take or refrain from taking action")). That is why a court must *always* apply the four-factor test before entering the

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did not "simply vacate[] the deregulation decision" and that APHIS's proposed measures operated to modify the deregulation order. Docket No. 50 at 15-16 (9th Cir. Mar. 27, 2008).

"extraordinary and drastic remedy" of an injunction absent explicit statutory direction otherwise. *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008); *see also* 28 U.S.C. §1292(a) (appeal of injunction is matter of right).

This Court's cases illustrate this principle. In *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982), for instance, it was not disputed on appeal that the Navy's training exercises involved "discharge[s] of pollutants," and that the Clean Water Act ("CWA") prohibited those discharges without a permit. *Id.* at 308-09. But even though the CWA thus prohibited the Navy's further training exercises of its own legal force, this Court entertained the Navy's challenge to the propriety of an injunction addressed to the same conduct, and reversed the First Circuit's decision mandating that injunction, without suggesting that the question was moot or that the government lacked standing to appeal. *Id.* at 311-19.

Ultimately, respondents' attempt to insulate the Ninth Circuit's decision from review altogether by attacking petitioners' standing to appeal suggests they had a different observation from their favorite "legal philosopher" (Resp.Br.23) in mind: "There must be some kind of way out of here." Bob Dylan, *All Along The Watchtower* (Columbia 1967). Alas for respondents, their standing argument gets them nowhere.

II. THE INJUNCTION IS FATALLY FLAWED

Respondents insist that this case involves merely a fact-bound disagreement over a district court's routine application of the four-factor test for injunctive relief. That suggestion is no more convincing now than it was in their brief in opposition to certiorari.

A. The Lower Courts Abdicated Their Duty To Adjudicate The Likelihood Of Irreparable Environmental Harm

Respondents argue that, because the lower courts recited the four-factor test, they must have applied it faithfully. *See generally* Resp.Br.25-35. The same argument was rejected in both *eBay* and *Winter*. *eBay*, 547 U.S. at 393-94; *Winter*, 129 S. Ct. at 374-82. And the argument likewise fails here.

The courts below proceeded on the premise that no serious inquiry into likelihood of irreparable harm is necessary to justify an injunction in a NEPA case pending the agency's preparation of an EIS. The district court stated that it was "not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it," and that such an inquiry "isn't [its] job." Pet.App.417a. The court then confirmed in its permanent injunction order that it would not "conduct ... the very same scientific inquiry it [had] ordered APHIS to do," Pet.App.68a; *see also* Pet.App.417a, and that an injunction is warranted in "'the run of the mill NEPA case,'" Pet.App.65a (citation omitted). The latter remark was not, as respondents suggest (Resp.Br.27), an "empirical observation"; it was the second sentence of a section of the court's opinion entitled "**LEGAL STANDARD**." Pet.App.65a. Further, the court's order relied explicitly on the Ninth Circuit's teaching in *Idaho Watersheds Project v. Hahn*, 307 F.3d 815 (9th Cir. 2002), that it would be "'odd'" to "'to conduct an extensive inquiry ... while the [government] conducts studies in order to make the very same scientific determinations.'" Pet.App.68a (quoting *Idaho Watersheds*, 307 F.3d at 831) (alteration in original).

The Ninth Circuit expressly adopted the same analytical framework. Although the court acknowledged that "[t]he parties' experts disagreed over virtually every factual issue relating to possible environmental harm," Pet.App.9a, it affirmed the district court's holding that petitioners "had [not] established any material issues of fact" necessitating a hearing *because* "the disputed matters [were] issues more properly addressed by the agency in the preparation of an EIS," Pet.App.17a-18a. And, like the district court, the Ninth Circuit invoked *Idaho Watersheds*' holding that, in a NEPA case, requiring such analysis by federal courts would improperly "duplicate the [agency's] efforts." Pet.App.18a-19a.[2]

Respondents suggest that, because this reasoning is contained in the part of the decision holding that petitioners could be deprived of an evidentiary hearing, it does not reflect how the court of appeals approached its injunctive relief analysis. Resp.Br.33. Not so. The Ninth Circuit's view that a district court need not trouble itself with resolving material disputes over the likelihood of irreparable harm before entering a

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[2] Following the Ninth Circuit's lead in this case, district courts under its supervision continue to believe that stand-still injunctions should reflexively issue in NEPA cases while additional environmental review is conducted. *See, e.g., Center for Food Safety v. Schaffer ("CFS")*, No. C 08-00484 JSW, Order at 7 (N.D. Cal. Mar. 16, 2010) (stating its initial inclination "while the environmental review is pending ... to order the Intervenor-Defendants to take all efforts, going forward, to use conventional seed" in a case involving Roundup Ready sugarbeets); *id.* at 4-5 (reasoning that *Geertson* calls for injunctive relief in any "typical NEPA case"); *see also* American Sugarbeet Growers Ass'n Br.7-8 (explaining that "*Geertson* had a pivotal, deleterious impact on the sugarbeet litigation").

NEPA-based injunction infected its entire analysis—and it explains why the panel majority was perfectly comfortable with the district court's express refusal to engage on that issue. Pet.App.1a-20a. Moreover, in reviewing the "Scope of the Permanent Injunction," Pet.App.10a (heading), the Ninth Circuit explicitly invoked its precedent holding that an injunction should issue in a NEPA case absent "unusual circumstances." Pet.App.12a; Pet.Br.30 n.10.

Respondents' effort to side-step *Amoco*, *Winter*, and *Weinberger* is also unavailing. It is irrelevant that *Amoco* and *Weinberger* involved an "appellate court [that] had overturned a district court" that refused to issue an injunction. Resp.Br.34. The courts erred in those cases not because they failed to respect the district courts' discretion, but because they directed injunctions without proof of irreparable injury. Thus, when this Court in *Winter* reversed the Ninth Circuit's *affirmance* of the district court's injunction, it found *Weinberger* and *Amoco* fully applicable. *Winter*, 129 S. Ct. at 374-82. The very same legal error pervades the lower courts' decisions in this case. By refusing to examine the likelihood of irreparable harm *themselves*—and instead punting that critical issue to APHIS's EIS process—the courts below improperly equated a procedural violation of NEPA with a finding of irreparable substantive harm. Pet.Br.27-33.

While respondents seem incredulous that anyone could interpret the decisions below as short-circuiting the requisite inquiry into likelihood of irreparable harm based on the finding of a NEPA violation, they urged the lower courts to do just that. Respondents told the district court that "'fail[ure] to evaluate the environmental impact' ... *by definition* constitutes

'irreparable injury,'" Docket No. 119 at 7 (N.D. Cal. Mar. 7, 2007) (emphasis added) (citations omitted), and they contended on appeal that "[i]n the NEPA context, procedural injury suffices to establish irreparable injury." Docket No. 38, at 38 (9th Cir. Feb. 25, 2008). That worked in the Ninth Circuit. But this Court has squarely rejected the notion that a procedural violation of NEPA or similar statutes creates a presumption of irreparable environmental harm, much less that such a procedural violation itself constitutes a harm justifying injunctive relief. *See* Pet.Br.26-27.[3]

B. The Injunction Is Not Based On A Requisite Injury To The Environment

Respondents do not answer petitioners' argument that respondents failed to demonstrate that *they* would be likely to suffer irreparable harm from continued planting of RRA—other than to admit that it is "common ground" that they were required to make that showing. Resp.Br.26. That showing is not only a traditional requirement for equitable relief, *see, e.g.*, *Winter*, 129 S. Ct. at 374, but also a prerequisite for standing to seek that relief. Pet.Br.40-41; *Lewis v. Casey*, 518 U.S. 343, 357-58 (1996). Because respondents undeniably failed to "establish[] that at least one identified [plaintiff] had suffered or would suffer harm," they lack standing to pursue equitable relief and the injunction must be vacated for that

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[3] Even in this Court respondents eventually slip into old habits and suggest that the "particular type of case" (here, NEPA) should make a difference in deciding whether injunctive relief is appropriate. Resp.Br.28 n.14. This Court has repeatedly rejected that argument in the very context in which this case arises.

reason alone. *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009).

Even if respondents could show that *they* had been harmed in some way, however, the injunction would still be invalid because the potential injuries they posit are not harms *to the environment*. Respondents do not dispute the FDA's conclusion that RRA is safe for humans and livestock. They do not contend that RRA cross-pollination (if it occurred) would injure any existing conventional alfalfa plant. And they recognize that occasional propagation from such cross-pollination (if that occurred) would not be a cognizable injury to the plant species, since "*isolated injuries to individual members* of an established species" are not, without more, environmental harm. Resp.Br.39.

Respondents insist that, because of cross-pollination with RRA, individual organic farmers may sometimes be unable to sell their produce *at an organic premium*. They have not shown that any organic farmers are likely to suffer meaningful levels of RRA cross-pollination or that the trace presence of RRA in organic crops has ever actually affected its market value. *See infra* at 15-16. But even if respondents could substantiate their fears, the diminution in the *price* that a seller's goods can fetch in the marketplace is a commercial harm, not an injury to the environment cognizable under NEPA.

Respondents protest that, although "NEPA is not intended to address 'economic or social effects * * * *by themselves*,'" where "those effects 'are interrelated' with 'natural or physical environmental effects,' agencies must consider them in an EIS." Resp.Br.40. But to fall within NEPA's scope, the economic or social effects must derive from an underlying harm to the

physical environment. In *Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 777-78 (1983), for example, continued operation of the Three Mile Island facility was "an event in the physical environment," but this Court refused to permit a NEPA challenge to it because that physical event was connected to alleged harm only through psychology. The same is true here. The interspersion of a trace of RRA in an organic farmer's fields would cause the *environment* no injury whatsoever, and the financial harm to the farmer, if any, would derive from the psychological preferences of organic consumers. The commercial protection of organic farmers is not an interest that NEPA was enacted to address (and such commercial harm would not be irreparable anyway).

Perhaps because potential effects on a farmer's sales price are so patently a commercial rather than environmental concern, respondents also invoke potential effects on the farmer's ability to grow the crops of his choosing. They adopt the district court's pronouncement that "'[f]or those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop.'" Resp.Br.41 (quoting Pet.App.44a) (alteration in original). That argument is unavailing.

First, a mere "possibility" that a harm could occur is *not* "tantamount" to that harm occurring. *See Metropolitan Edison Co.*, 460 U.S. at 775 ("A risk is, by definition, unrealized in the physical world."). *Second*, individual instances of cross-pollination are not "tantamount" to the elimination of all conventional alfalfa. *Third*, to the extent it affects any interest that

is not wholly commercial, the disappointment of an organic farmer's desire to grow 100% RRA-free alfalfa would not inflict any injury *on the environment.*

NEPA injunctions are not available for intangible injuries that are purely ideological or based on policy objections to federal action, no matter how intensely held. *Weinberger*, 456 U.S. at 311-12; *Metropolitan Edison Co.*, 460 U.S. at 777. And although respondents sought the injunction because they "fear" that RRA could "caus[e] conventional alfalfa to disappear," Pet.App.4a, even respondents now acknowledge that "plaintiffs' *fear* of an environmental impact" is "non-cognizable" under NEPA. Resp.Br.41 n.20.

C. Respondents Have Not Established A Likelihood Of Irreparable Harm

Respondents insist that the injunction is grounded on a finding of the requisite "likely" irreparable harm.[4] But respondents do not deny that when the district court found a "*sufficient[]* likel[ihood]" of irreparable harm (before *Winter*), Ninth Circuit law deemed a mere "possibility" of such harm sufficient. Pet.Br.41-42

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[4] Respondents claim that "likely" cannot possibly mean "'more likely than not.'" Resp.Br.36 n.18. *Webster's* begs to differ. *Webster's Third New International Dictionary* 1310 (1993) (defining "likely" as "having a better chance of existing or occurring than not" (definition 2b)); *see also Amoco Production Co. v. Village of Gambell*, 480 U.S. 531, 545 (1987) (stating alleged irreparable harm must be "probable"). Indeed, just one month before they filed this brief, two respondents conceded that "'[l]ikely' means 'having a better chance of existing or occurring than not.'" *CFS*, Reply in Support of Mot. for Prelim. Inj. at 17 n.28 (N.D. Cal. Feb. 19, 2010) (citation omitted). At any rate, the harm alleged here is at best "possible" and exceedingly *unlikely*. That is plainly insufficient under *Winter*. 129 S. Ct. at 374-75.

(emphasis added). Respondents also do not deny that the district court consistently used language connoting mere possibility, describing "potential" harms that "could" occur. Pet.Br.41-42, 44-45. Respondents slip and use the same language when describing their arguments and evidence.[5]

Most important, respondents do not account for the overwhelming record evidence that any cognizable harm from the continued use of RRA is extremely *un*likely. Respondents do not dispute the scientific evidence that cross-pollination from RRA grown for hay—accounting for more than 90% of RRA—is "virtually non-existent" (Pet.App.229a) or "essentially zero" (Pet.App.164a). Pet.Br.42-45. Nor do respondents contend that cross-pollination from RRA hay crops has *ever* occurred or that it is at all likely to occur. Respondents do suggest that "unpredictable weather" might prevent harvesting before bloom and "increase[] the probability" of cross-pollination. Resp.Br.11. But to be clear, to risk any cross-pollination from hay one would have to hypothesize several *weeks* if not *months* of rain—enough to prevent the mowing of both hay fields before flowering *and* further to prevent the mowing of the conventional field while a seed was maturing (which itself takes months). That is why the experts testified that the possibility of cross-pollination from hay with APHIS's measures in place is virtually zero. Pet.Br.43-45.

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[5] *See, e.g.*, Resp.Br.11 ("human error could cause inadvertent contamination"); Resp.Br.12 ("may cause contamination"); *id* ("may not be able to cut"); Resp.Br.13 ("potential for human error"); Resp.Br.29 ("other circumstances that could impair the effectiveness of APHIS's proposed conditions"); Resp.Br.41 ("potential economic injury").

Respondents also fail to rebut the scientific evidence that, with use of APHIS's proposed stewardship measures, meaningful cross-pollination from RRA seed crops is distinctly *im*probable. Pet.Br.45-47.[6] Respondents point to third-hand anecdotal accounts involving two growers, Dairyland and Cal/West. Those accounts went untested because petitioners never were afforded an evidentiary hearing and opportunity to cross-examine the witnesses who repeated them. But even if they were credited, the accounts at most demonstrate only that some non-organic farms experienced low levels of RRA cross-pollination. Dairyland, for example, allegedly detected RRA cross-pollination at levels ranging only from "trace" to 0.9%. JA-1018, 1024. This cross-pollination affected only 11-16 of Dairyland's roughly *thousand or more* fields. Pet.App.398a-400a, 408a. Because Dairyland's contracts and internal standards permitted levels of "adventitious presence" of up to 1%, this

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[6] Respondents argue that, under the CEQ regulations, even immaterial adverse impacts on the environment categorically require an injunction whenever a procedural violation of NEPA is shown. Resp.Br.49-50. But there is no reason to read the regulations' reference to "an adverse environmental impact" (40 C.F.R. §1506.1(a)(1)) to include *immaterial* impacts. And this Court's precedents make clear that they cannot be given that absurd reading. Indeed, in *Winter* this Court held that the injunction at issue was not required pending the completion of an EIS even though the Navy's own EA estimated that the training exercises at issue would "result in 564 instances of physical injury including hearing loss ... and nearly 170,000 behavioral disturbances." *Winter*, 129 S. Ct. at 392 (Ginsburg, J., joined by Souter, J., dissenting); *see id.* at 372; *see also Weinberger*, 456 U.S. at 311 (the extraordinary remedy of injunction is not available for injuries that are "'merely trifling'") (citation omitted).

cross-pollination was immaterial and caused no harm. Pet.App.407a. Nor do respondents contend otherwise.

The Cal/West allegations involve only two alleged instances of cross-pollination, neither of which caused any harm. The first instance was similarly at immaterial levels (0.1-0.3%). Pet.App.405a. And the second only exceeded 1% (0.5-1.5%) because the crop was inadvertently planted a mere *200 feet* from an RRA seed field—far closer than allowed under APHIS's proposed isolation distances of 1500 feet and three miles. Pet.App.161a, 406a; JA-673. And even that experience caused no actual harm. Pet.App.406a. Cal/West specifically consented to leaving the fields in place for the 2005 growing season precisely because—far from representing a dire threat—it neither caused nor threatened any harm. *Id.*

Ultimately, respondents do not contest that "[t]here is no evidence that *any* farmer lost *even a single* sale" or that no grower has "ever lost organic certification." Pet.Br.3, 39. Indeed, they admit that, even though RRA was planted for 21 months without any government restrictions, tangible harm from cross-pollination has "yet to occur." Resp.Br.41. It is difficult to think of more probative evidence of the *absence* of a likelihood of irreparable harm while an EIS is prepared under APHIS's proposed restrictions.

Lacking any evidence of likely irreparable harm, respondents hypothesize various scenarios whereby cross-"contamination" of non-RRA alfalfa stocks *could* occur, such as by "flooding," seed spillage during transport, "accidental seed mixing ... within a seed processing facility," "inadequate equipment cleaning," from "feral alfalfa," or by the actions of "[w]ild pollinators." Resp.Br.11-13 & n.7. Even the Ninth

Circuit and district court in this case placed no weight on these possibilities, since none are likely to have much impact. Pet.App.235a-39a, 397a-98a, 413a.[7] The mere enumeration of potential risks does not satisfy respondents' burden to prove likely irreparable harm.

While respondents continue to suggest that the use of RRA could "irreversibly alter[]" alfalfa (Resp.Br.38) and, indeed, even lead to the "elimination of all alfalfa" (Resp.Br.41), they provide no evidence to support this science fiction-like hypothesis. And respondents certainly point to no evidence that such an extinction event is "likely." *See* Pet.Br.34-35. Nor could they. Even the district court recognized that RRA's market presence was expected to increase at most to 5% while the EIS was being prepared. Pet.App.64a; JA-621. RRA's only selective advantage is glyphosate resistance, Pet.App.398a, which is no advantage at all in the fields of organic farmers who do not use glyphosate. Pet.App.263a-64a, 401a. And farmers who want to prevent intermixing of RRA with their conventional or organic crops can easily and inexpensively test for RRA presence and take measures to eliminate any RRA from their stocks. Pet.App.181a-83a, 262a, 277a, 410a-11a; JA-623-24.

Finally, respondents err in suggesting that petitioners' willingness to accept APHIS's proposed injunction means that petitioners have conceded that RRA poses "at least some degree of irreparable harm." Resp.Br.31 n.15, 37-38. In *Winter*, the Navy similarly

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[7] The lower courts also rightly ignored respondents' anecdotal stories of cross-pollination involving other genetically engineered crops and grasses, *e.g.*, Resp.Br.13, 39, because those crops have different biologies, methods of pollination, and customary stewardship measures. Pet.App.380a-85a.

focused its argument on the absence of likely irreparable harm with certain uncontested protective measures in place. 129 S. Ct. at 376. As in *Winter*, petitioners' decision to accept a *tailored* injunction does not concede the existence of likely irreparable harm in the absence of an injunction, much less the validity of the blanket injunction at issue.[8]

D. The Injunction Is Vastly Overbroad

Respondents do not dispute that the district court had an obligation to narrowly tailor relief. Pet.Br.47-50. This duty required the court to consider APHIS's proposed measures, including isolation distances. *Id.* Respondents do not contest that "*some* isolation distance would prevent any possibility of cross-pollination." Pet.Br.49. To the contrary, they have expressly acknowledged in recent EIS Comments that "*[r]easonable alternatives* may exist for mitigating these risks [of cross-pollination], *such as isolation distances* and geographic restrictions." USDA-APHIS, Docket No. APHIS-2007-0044, Comments of Center for Food Safety at 8 (Mar. 3, 2010) (emphasis added). And earlier in this litigation respondents conceded "'5-mile' or 'several miles' isolation distances

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[8] Some of respondents' *amici* suggest, as an alternative rationale for the injunction, that further RRA planting may hasten the development of weeds resistant to glyphosate. The district court did not so find, and even respondents do not advance that argument here. For good reason. There is no evidence that the predicted expansion of RRA to a 5% market share during the period before an EIS is issued would in and of itself have any appreciable effect on the development of glyphosate-resistant weeds, and there are time-honored means of protecting against the risk of the development of weed resistance in any event. Pet.App.401a; JA567-70.

would establish a 'zero tolerance' standard." Pet.Br.49 (citation omitted). Yet, after rejecting APHIS's proposal, the district court categorically refused to "get into ... isolation distances" (Pet.App.192a) and enjoined all cultivation of RRA—anywhere—even where it is hundreds of miles away from any conventional or organic crop. Pet.Br.49.

Respondents suggest that the court was justified in rejecting APHIS's particular proposal because no deference is owed an agency's expert judgment outside the context of an administrative rule or order. Resp.Br.46-48. The better view is that the expert agency's proposed measures were entitled to deference. US.Br.35-38; *see Winter*, 129 S. Ct. at 377-78 (relying on expert affidavits from Navy officers). But in any event, the district court erred in failing to consider APHIS's proposed measures because a district court *always* has a duty to consider whether a narrower injunction would be sufficient and there was no evidence that irreparable harm was likely with APHIS's proposed measures in place. *Supra* at 13-18.

E. This Court Should Remand With Instructions To Enter APHIS's Proposed Remedy

Because the record fails to establish a likelihood of irreparable environmental harm under APHIS's proposed injunction, this Court should reverse and order the court of appeals to direct the district court to enter those terms on remand. Such specific instructions would not intrude on the "equitable discretion [of a] district court[]," Resp.Br.50, because district courts have no discretion to impose injunctive relief unnecessary to prevent likely irreparable harm. *Winter*, 129 S. Ct. at 374-75. This Court thus had no

difficulty in *Winter* expressly vacating the injunction "to the extent it has been challenged by the Navy." *Id.* at 382. The same result should obtain here. Indeed, the Ninth Circuit has already refused to heed this Court's decision in *Winter*. Pet.Br.21, 41. And the ill-conceived injunction at issue has already been in place for *three years*. There is no reason to send this case back to the Ninth Circuit for more delay.

III. AN EVIDENTIARY HEARING WAS REQUIRED IN THIS CASE

The government and respondents have no response to petitioners' demonstration that the Federal Rules of Civil Procedure required an evidentiary hearing before the district court could resolve any genuine factual dispute over the likelihood of irreparable harm. Pet.Br.24-25, 51-57. Indeed, they avoid even mentioning or citing the Federal Rules. Resp.Br.51-59; U.S.Br.39-42. The absence of any response concedes what the text makes clear: absent waiver the Federal Rules require district courts to resolve genuine disputes of material fact through evidentiary hearings. *See* Fed. R. Civ. P. 56. Because Congress clearly has the authority to require the courts to provide procedural safeguards above the constitutional floor, there is no need to determine whether petitioners were also entitled to a hearing as a matter of due process. *Cf. Northwest Austin Mun. Util. Dist. No. One v. Holder*, 129 S. Ct. 2504, 2513 (2009).

In any event, an evidentiary hearing was required as a matter of due process as well. The government acknowledges that trial-based adversarial proceedings are generally required whenever there are genuine disputes over material issues of fact and that this requirement applies with full force to remedial

proceedings. U.S. Br.39. But the government and respondents ask the Court simply to carve-out a categorical exception for suits filed under the APA. That argument should be rejected.

First, respondents are mistaken in suggesting that the right to an evidentiary hearing in equitable proceedings lacks sufficient historical pedigree. Respondents admit that this right was originally codified in the Judiciary Act of 1789 and that, while a statute passed in 1802 permitted equity courts to revert to decision on written depositions for the first half of the nineteenth century, "[t]estimony in open court" was "introduced with ... rigor in equity trials" in "1848, with the merger of law and equity under the Field Code." Resp.Br.53-55. These developments led Congress in 1912 to restore the federal statutory right to hearings in equity—a right that has been recognized continuously for an unbroken 98-year period. Neil Fox, Note, *Telephonic Hearings in Welfare Appeals: How Much Process is Due?*, 1984 U. Ill. L. Rev. 445, 452 (1984). And the lower courts have widely recognized that the "cardinal principle" that material factual disputes must be resolved through evidentiary proceedings applies to material disputes bearing on injunctive relief as well. *E.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 101 (D.C. Cir.) (en banc), *cert. denied*, 534 U.S. 952 (2001).[9]

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[9] Respondents' effort (Resp.Br.56) to distinguish *Microsoft* is unavailing. The en banc D.C. Circuit's recognition that parties are entitled to an evidentiary hearing to resolve material issues of disputed fact bearing on the entry of injunctive relief was not even arguably limited to the facts of that case or the impact of the proposed relief there. *See Microsoft*, 253 F.3d at 101 (noting exception only for TROs).

Second, the government and respondents improperly ignore fundamental constitutional distinctions between Article III courts and administrative agencies when they insist that due process requires no more in a case challenging agency action than in the underlying administrative proceedings. This Court has approached due process constraints on *agency* action by asking what "*judicial-type procedures* must be imposed upon *administrative action* to assure fairness." *Mathews v. Eldridge*, 424 U.S. 319, 348 (1976) (emphasis added); *see also Goldberg v. Kelly*, 397 U.S. 254 (1970) (extending judicial requirement of evidentiary hearings and cross-examination to administrative welfare proceedings). But the Court has never suggested that whatever is sufficient for an agency is good for the *courts* too.

Third, the government's distinction between disputes involving "scientific" and "economic" facts, and those involving "assessments of the credibility" or "accuracy of fact witnesses to historical events," U.S.Br.40-42, cannot withstand scrutiny. Federal courts routinely deny summary judgment and require trial-based, adversarial proceedings to resolve scientific disputes between experts. And this Court has forcefully rejected the "overly pessimistic [view] about the capabilities ... of the adversary system" to address scientific and technical issues and made clear that "[v]igorous cross-examination" is key to resolving disputes between experts. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

If this Court concludes that there are any material issues of disputed fact that would stand in the way of remanding with instructions to enter APHIS's proposed injunction, an evidentiary hearing is

necessary to resolve those issues. For example, such a hearing would allow each side to cross-examine the other's experts and also allow petitioners to cross-examine the lay witnesses who provided hearsay anecdotal accounts of isolated incidents of cross-pollination. Because the district court refused to conduct an evidentiary hearing before entering its injunction, petitioners were never able to test those allegations through the rigors of cross-examination.

Ultimately, the government betrays its true concern as not legal but practical—the purportedly "significant costs on the government" that evidentiary hearings impose. U.S.Br.42 n.15. But a party's due process rights cannot be sacrificed for another party's desire to avoid the inconveniences or burdens of the adversary process. *See, e.g., Stanley v. Illinois*, 405 U.S. 645, 656 (1972). And neither the government nor respondents has provided any principled basis for depriving litigants of their right to an evidentiary hearing to resolve disputed issues of material fact bearing on whether an injunction is appropriate.

CONCLUSION

The judgment of the court of appeals should be reversed, and the case remanded with instructions to vacate the district court's injunction and enter APHIS's proposed remedy in its place.

Respectfully submitted,

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AMICUS CURIAE BRIEF

Supreme Court, U S
FILED
MAR 8 - 2010
OFFICE OF THE CLERK

No. 09-475

In the Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF AMERICAN FARM BUREAU FEDERATION, BIOTECHNOLOGY INDUSTRY ORGANIZATION, NATIONAL ALFALFA AND FORAGE ALLIANCE, AMERICAN SEED TRADE ASSOCIATION, NATIONAL COTTON COUNCIL, NATIONAL POTATO COUNCIL, AMERICAN SOYBEAN ASSOCIATION, AND NATIONAL ASSOCIATION OF WHEAT GROWERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

The American Farm Bureau Federation ("Farm Bureau") is a general farm organization representing over 6.2 million member families.[1] Farm Bureau was established in 1919 to protect, promote, and represent the business, economic, social, and educational interests of American farmers and ranchers. Farm Bureau policy, which is developed through a member-controlled, grassroots process, supports the use of agricultural biotechnology, as well as conventional and organic farming.

The Biotechnology Industry Organization ("BIO"), created in 1993, is the world's largest biotechnology trade association. Its mission is to champion biotechnology on behalf of its 1,200 members—a wide range of entities that are involved in the research and development of numerous innovative biotechnologies. Through its Food and Agriculture Section, BIO has taken the lead in promoting the safety and benefits of genetically engineered crops developed through agricultural biotechnology. BIO advocates for scientific regulatory approaches for these crops both domestically and abroad, while also supporting the concurrent cultivation of conventional and organic crops.

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[1] Pursuant to Supreme Court Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and no person other than *amici*, their members, or their counsel made a monetary contribution to the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, the parties' letters consenting to the filing of this brief have been filed with the Clerk's office.

The National Alfalfa and Forage Alliance ("NAFA") is dedicated to ensuring that all segments of the alfalfa and forage industry can compete effectively and profitably, domestically and abroad. NAFA's objective is to be a forum for consensus building among various stakeholders, and to be an effective advocate on behalf of the alfalfa and forage industry. NAFA strongly supports the availability and continued use of agricultural biotechnology, and believes that science-based stewardship management practices allow for the coexistence of different markets and methodologies in production agriculture.

The American Seed Trade Association ("ASTA") is a voluntary, nonprofit national trade association representing approximately 740 members involved in seed production and distribution, plant breeding, and related industries in North America. ASTA's mission is to enhance the development and movement of quality seed worldwide. Many ASTA members are research-intensive companies engaged in the discovery, development, and marketing of enhanced seed—*i.e.*, seed that has been modified to manifest certain beneficial or desirable traits.

The National Cotton Council ("NCC") is the central organization of the U.S. cotton industry, representing producers, ginners, oilseed crushers, merchants, cooperatives, textile manufacturers, and cottonseed handlers and merchandisers in 18 States stretching from California to the Carolinas. Annual cotton production, averaging approximately 20 million 480-pound bales, is valued at more than $5 billion at the farm gate. In addition to the cotton fiber, cottonseed products are used for livestock feed and cottonseed oil is used for food products ranging from margarine to salad dressing. Collectively, the an-

nual economic activity generated by cotton and its products in the U.S. economy is estimated to be in excess of $120 billion.

The National Potato Council ("NPC") is a non-profit trade association representing more than 90 percent of U.S. potato production. NPC growers produce both seed potatoes and potatoes for consumption in a variety of forms, within all 34 States where commercial production occurs. NPC's mission is to provide a unified voice for the U.S. potato industry on national legislative, regulatory, environmental, and trade issues, and to promote increased profitability for growers and greater consumption of potatoes.

The American Soybean Association ("ASA") is the national, not-for-profit trade association that represents U.S. soybean farmers on domestic and international issues of importance to the soybean industry. ASA's advocacy and representational efforts are made possible through the voluntary membership in ASA of over 22,500 farmers in 31 States where soybeans are grown. ASA also develops domestic and foreign markets for U.S. soybeans and soy products.

The National Association of Wheat Growers ("NAWG") is a federation of 21 state wheat grower associations that works to represent the needs and interests of wheat producers before Congress and federal agencies. Based in Washington, D.C., NAWG is grower-governed and grower-funded, and recognizes the benefits and value that could be created within the wheat chain through the prudent application of biotechnology.

Farm Bureau, BIO, NAFA, ASTA, NCC, NPC, ASA, and NAWG support the continued application of advances in agricultural biotechnology like the genetically engineered alfalfa at issue in this case. Sustained progress in this important field requires a firm commitment to science-based regulations and policies. When the judiciary has occasion to review the regulation of agricultural biotechnology, its decisions likewise must be based on scientific evidence, not anecdotes and speculation. Because the courts below did not weigh the equities using the best available evidence, *amici* have a compelling interest in this Court's determination of whether the lower courts' injunction was proper.

INTRODUCTION AND SUMMARY OF ARGUMENT

Although the context of its decisions has varied over the decades—ranging from wartime price-control laws to internet auction houses—this Court has consistently held that an award of injunctive relief requires application of the well-established balancing test historically employed by courts of equity. The same rule should apply in the context now before the Court—the practical application of agricultural biotechnology.

The specific crop at issue in this case, a genetically engineered variety of alfalfa known as "Roundup Ready®," is the product of extensive research and testing conducted over the course of many years. Like any other agricultural biotechnology product, Roundup Ready® alfalfa was subject to a thorough, science-based regulatory review and approval process by multiple federal agencies before it went into commercial use. The district court concluded, however, that the U.S. Department of Agriculture

("USDA") failed to adequately study the potential environmental impacts of its decision to deregulate Roundup Ready alfalfa, and without further analysis the court issued a nationwide ban on the planting and sale of that alfalfa.

Despite this Court's consistent and important line of decisions emphasizing the "extraordinary" nature of injunctive remedies, the district court did not fulfill its obligation to balance harms and reconcile conflicting interests before issuing its injunction. Rather than conducting the sort of evidentiary hearing needed to examine the copious scientific evidence relevant to the plaintiffs' alleged irreparable injuries, the district court blithely accepted the plaintiffs' anecdotal assertions of harm. Nor did the court make any real effort to fashion an injunction that would take into account the interests of the many innocent farmers who were relying on the availability of genetically engineered alfalfa, or adjust for the impact of an expansive injunction on the entire agricultural biotechnology industry.

The district court, and later the court of appeals, justified these shortcuts by asserting that the balance of harms would be dealt with when the government prepared a new environmental study. This rationale effectively creates a special exception to the traditional test for injunctive relief in cases arising under the National Environmental Policy Act ("NEPA"). Nothing in either court's decision reflects a recognition that this Court has repeatedly rejected these sorts of special exceptions to the traditional equitable balancing test. Indeed, using the environmental-review process as a substitute for historical injunctive standards is particularly inappropriate when dealing with agricultural biotechnology—a

field where reams of relevant scientific data are readily available to the court.

To protect the farmers who choose to grow genetically engineered crops, as well as the public benefits that agricultural biotechnology brings to producers and consumers around the world, this Court should reverse the lower courts' injunction.

ARGUMENT

I. THE LOWER COURTS FAILED TO BALANCE PUBLIC INTEREST AND PRIVATE NEEDS BEFORE APPROVING AN EXPANSIVE INJUNCTION.

The first commercial plantings of genetically engineered crops occurred in 1996. By 2009, 14 million farmers had planted more than 330 million acres in 25 different countries. See Clive James, *Global Status of Commercialized Biotech/GM Crops: 2009* (Feb. 2010), http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp. The rapid development and delivery of benefits from agricultural biotechnology into the commercial marketplace have been incredible. The USDA now estimates that 91% of soybeans, 88% of cotton, and 85% of corn in the United States are the product of biotechnology. Pet. App. 258a-259a. The injunction in this case threatens that progress. By abruptly halting the planting and sale of a genetically engineered crop, without accounting for harms to farmers or the public interest, the lower courts have acted contrary to this Court's precedent and created uncertainty for almost every stakeholder in the agricultural biotechnology industry.

A. An Injunction Is A Tool For Reconciling Competing Interests, Not An Automatic Award To The Prevailing Party.

The lower courts accurately recited the basic four-factor test for issuance of a permanent injunction. A plaintiff seeking such relief must establish "(1) that it has suffered an irreparable injury; (2) that remedies available at law * * * are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay, Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); see Pet. App. 11a.[1] But paying lip service to the established standard is a far cry from applying it appropriately, and in a manner that reflects a full understanding and acceptance of this Court's precedent.

The mere fact that federal courts have the power to "ensure compliance with a statute" does not mean that judges are "mechanically obligated to grant an injunction for every violation of law." *Amoco Prod. Co.* v. *Village of Gambell*, 480 U.S. 531, 542 (1987) (quoting *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 313 (1982)). Rather, as the traditional four-factor test itself indicates, an injunction is "the instrument for nice adjustment and reconciliation be-

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[1] "The standard for a preliminary injunction is essentially the same as for a permanent injunction, with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success." *Amoco Prod. Co.* v. *Village of Gambell*, 480 U.S. 531, 546 n.12 (1987). Accordingly, cases discussing preliminary-injunction standards are generally applicable in the context of the permanent injunction at issue here.

tween the public interest and private needs as well as between competing private claims." *Hecht Co.* v. *Bowles*, 321 U.S. 321, 329-330 (1944). This means that courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Winter* v. *Natural Res. Def. Council, Inc.*, 129 S.Ct. 365, 376 (2008) (quoting *Amoco*, 480 U.S. at 542). Courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id.* at 376-77 (quoting *Romero-Barcelo*, 456 U.S. at 312).

The question in this case is not whether the lower courts superficially acknowledged the four factors that must be addressed before an injunction may issue. They did. The real question is whether the courts' reasoning demonstrates that they actually applied a test quite different from the one approved by this Court. Because it would have been impossible for the lower courts to apply this Court's test without a fuller consideration of the available scientific evidence and the public importance of agricultural biotechnology, the answer to this question could not be more plain.

B. The Lower Courts Effectively Presumed Irreparable Harm To The Plaintiffs By Ignoring Key Data And Established Farming Practices.

1. Deciding whether irreparable injury is likely requires consideration of the best available evidence.

In *Winter*, this Court reiterated that a plaintiff seeking to enjoin allegedly harmful activities must "demonstrate that irreparable injury is *likely* in the

absence of an injunction." 129 S.Ct. at 375. Whether a plaintiff can make this showing depends in large measure on the type of evidence that is available in a given case. If a plaintiff were to claim, for example, that building a new shopping mall in the midst of his favorite recreational area would permanently impair his use and enjoyment of the land, a signed affidavit to that effect might be sufficient to prove irreparable injury. In a case like this one, however, the injunction affects a genetically engineered product that has undergone thorough review by federal agencies, is supported by extensive scientific testing, and is in widespread use throughout the United States. The alleged harms occur, moreover, at a genetic level not readily observable by an affiant. The type of anecdotal injury reports proffered by the plaintiffs accordingly cannot and should not be the sole basis of a nationwide injunction.

No one disputes that the district court had before it substantial scientific evidence addressing the likelihood that the continued use of Roundup Ready alfalfa would *not* irreparably harm the plaintiffs. This evidence includes a number of field studies that have measured the gene flow between Roundup Ready alfalfa and conventional alfalfa using various "isolation distances" between plantings.[2] These studies, which were conducted under worst-case-scenario conditions that allowed for more gene flow than would occur in the more likely real-world conditions, demonstrate

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[2] To maintain the status quo while it conducted the environmental review ordered by the district court, the government proposed certain "stewardship measures," including minimum isolation distances between plantings, that were designed to prevent Roundup Ready alfalfa from coming into contact with conventional and organic alfalfa. Pet. App. 64a-65a.

that the risk of cross-pollination feared by the plaintiffs is negligible. See, *e.g.*, Pet. App. 228a-229a. More specifically, the studies show that gene flow was less than 0.1% for alfalfa being grown for seed and approximately 2.5 in a million (or 0.00025%) for alfalfa being grown for hay. See, *e.g.*, *id.* at 168a-183a, 280a-281a.[3]

The traditional four-factor test demands consideration of the *likelihood* of irreparable injury. Such likelihood is best assessed when objective, measurable data are available. Although in some cases concrete numeric or probabilistic data may be hard to come by, the years of federally regulated research and testing that led up to the deregulation of Roundup Ready alfalfa provided the courts below with precisely that sort of information. Thus, notwithstanding the plaintiffs' assertion that "genetic contamination" had already taken place (Pet. App. 13a), the lower courts were not free to ignore field-testing data showing that the harms feared by the plaintiffs were in fact a long way from "likely." When a court has failed to review the best available evidence presented by both sides, as the district court did here, it has not made a genuine effort to balance the equities before issuing an injunction.

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[3] The studies presented to the district court also ruled out any realistic possibility that glyphosate-resistant weeds would develop during the period of the injunction (JA 568-570)—a claim that the lower courts did not cite in support of their decisions, but that the plaintiffs have sought to revive in this Court (Br. in Opp. 5).

2. Cross-pollination with genetically engineered crops does not constitute irreparable injury.

In addition to addressing the best evidence concerning the likelihood of harm, courts must ask whether the evidence supports the plaintiffs' claims that their alleged injuries would truly be irreparable. As this Court observed in *Amoco*, harm is not irreparable unless it is "permanent, or at least of long duration," and not redressable through payment of monetary damages. 480 U.S. at 545. Here, the court of appeals opined that "contamination was irreparable harm because [it] cannot be reversed and farmers cannot replant alfalfa for two to four years." Pet. App. 13a. This conclusion ignores basic facts and scientific evidence concerning agricultural biotechnology.

The plaintiffs' "contamination" claim boils down to an assertion that anything less than 100% varietal purity constitutes *per se* irreparable harm to organic and conventional alfalfa farmers. Pet. App. 71a. This argument, which both the district court and the court of appeals accepted unquestioningly, misunderstands some fundamental truths about agriculture. Farming practices are not designed to achieve total genetic purity, whether the crop is genetically engineered or not. Indeed, the USDA's National Organic Program does not require genetic purity for organic certification. *Id.* at 263a-264a, 283a-284a. Add to that the fact that Roundup Ready alfalfa does not have any adverse health or environmental effects (*id.* at 43a), and it becomes clear that minute levels of cross-pollination do not meet any reasonable definition of "harm."

Even if the loss of purity were harmful in some meaningful sense, moreover, there would be no reason to consider such an injury "irreparable." Workable methods exist for reversing the effects of a loss of purity within one growing season. *Id.* at 410a-411a. And any economic harm that might accrue to farmers who receive premium prices for specialty products that claim to be free from agricultural biotechnology could be recovered through money damages. The lower courts thus acted on the unsupported assumption that any type of genetic "contamination" would qualify as an irreparable injury, when in fact such cross-pollination, to the extent it qualifies as harm at all, can be fully addressed by measures far less extreme than the nationwide injunction issued by the district court.

3. **A finding of irreparable injury should not be based on a presumption that alleged harms cannot be mitigated.**

The district court based its irreparable-harm finding at least in part on the belief that the government's proposed "stewardship requirements" were unenforceable. Pet. App. 69a-70a. The court of appeals explicitly endorsed that finding. *Id.* at 13a. Like other aspects of the injury determination below, this conclusion stems from mistaken assumptions rather than actual evidence. In reality, neighboring farmers have been successfully cultivating reproductively compatible crops with different genetic traits since long before the advent of agricultural biotechnology. The implementation of these "coexistence" practices demonstrates the likely success of the USDA's proposed stewardship requirements for Roundup Ready alfalfa.

Field corn and popcorn provide a good example of how farmers growing different crops have learned to coexist. Although these two corn varieties are capable of cross-pollinating, each has unique genetic traits that would damage the other crop's value if they were permitted to commingle. Yet farmers commonly plant field corn and popcorn in the same geographic regions. To prevent unwanted gene flow, field corn and popcorn farmers cooperate in employing management techniques that have long allowed them to coexist and prosper. See, *e.g.*, B. Rosie Lerner & Michael N. Dana, *Growing Sweet Corn* (May 2001), http://www.hort.purdue.edu/ext/HO-98.pdf. The same sorts of techniques, including the types of stewardship requirements proposed by the USDA in this case, also have allowed conventional, organic, and genetically engineered crops to coexist. Published studies confirm that such coexistence need not cause economic or commercial hardship for farmers. See, *e.g.*, Graham Brookes & Peter Barfoot, *Co-Existence in North American Agriculture: Can GM Crops be Grown with Conventional and Organic Crops?* (June 2004), http://www.pgeconomics.co.uk/pdf/CoexistencereportNAmericafinalJune2004.pdf.

The lower courts made no effort to grasp the implications of these longstanding farming practices, to digest the relevant studies, or to review any other evidence concerning coexistence. Instead, their finding of irreparable harm rested on the implicit assumption that farmers are incapable of complying with mandatory stewardship measures and the explicit determination that the government could never enforce such requirements. This reliance on severely flawed assumptions, rather than available evidence, is yet another way in which the district court and

court of appeals departed from this Court's clear standards for injunctive relief.

C. The Lower Courts' Injunction Did Not Adequately Account For The Severe Hardships Borne By Innocent Alfalfa Farmers.

More than 20 million acres of alfalfa are grown in the United States each year, making it the fourth largest crop in the country. Pet. App. 330a. When the district court enjoined the planting and sale of Roundup Ready alfalfa, many alfalfa growers had already made irreversible investment decisions based on the reviews completed by federal government agencies and the ready availability of that product—purchasing new equipment (often with borrowed funds), cancelling crop insurance, and entering into long-term alfalfa supply contracts. The court's injunction threw these plans into disarray, causing both concrete economic dislocations and incalculable hardship and distress for alfalfa farmers and their families.

To the extent that it considered these hardships at all, the district court brushed them aside as stemming from the "desire of some farmers to plant *more* Roundup Ready alfalfa or to *switch to* Roundup Ready alfalfa." *Id.* at 72a. But farming is not undertaken on a whim; the farmers affected by the injunction had made plans and investments far in advance of the district court's adverse rulings, in reliance on the government's decision to deregulate Roundup Ready alfalfa. The upshot is that innocent alfalfa farmers—people who were simply buying genetically engineered seed that had been reviewed and deregulated by the USDA—were penalized by the district court's expansive injunction.

The problem with this outcome is not merely that the district court failed to properly weigh the hardship innocent alfalfa farmers would suffer as a result of the injunction. The deeper flaw is the lower courts' failure to take seriously their responsibility to balance "competing claims of injury" (*Winter*, 129 S.Ct. at 376), especially injuries to parties not responsible for the statutory violation at issue. "The historic injunctive process was designed to deter, not to punish." *Romero-Barcelo*, 456 U.S. at 310 (quoting *Hecht*, 321 U.S. at 329-330). Because NEPA is a procedural statute that does not mandate "particular results" (*Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 350, 353 n.16 (1989)), the district court's conclusion that the government must prepare an Environmental Impact Statement ("EIS") for Roundup Ready alfalfa addressed the government's procedural failures. Pet. App. 51a-52a. The extra step of prohibiting the planting and sale of Roundup Ready alfalfa punished innocent parties, and did nothing to deter future procedural violations by the government. See *Romero-Barcelo*, 456 U.S. at 312-314.

The district court's reflexive grant of broad injunctive relief is an all too common phenomenon. Especially in NEPA disputes, courts often have considered injunctive relief to be virtually automatic in the "run of the mill" case. Pet. App. 55a. But that attitude is inconsistent with this Court's precedent—even when it is camouflaged by citations to *Winter* and *eBay*. Courts adjudicating NEPA suits must strive to erase any bias in favor of issuing whatever injunction may be requested by the prevailing party, which has no *right* to that extraordinary remedy. *Winter*, 129 S.Ct. at 376. The basic statutory violation in a NEPA case can be cured by ordering the of-

fending government agency to prepare a new environmental study. The court's job in fashioning an injunction while that study takes place is "to arrive at a nice adjustment and reconciliation between the competing claims" of the affected parties. *Romero-Barcelo*, 456 U.S. at 312 (internal quotation marks omitted); see *Winter*, 129 S.Ct. at 376-377.

The injunction issued by the district court in this case, and approved by the court of appeals, instead stems from an improper predisposition to grant injunctive relief. Regardless of the cases they cited, the lower courts did not make a serious effort to tailor an injunction that would account for hardships to the many farmers who planned to grow Roundup Ready alfalfa.

D. The Lower Courts Improperly Downplayed The Strong Public Interest In Broader Application Of Agricultural Biotechnology.

In addition to balancing competing private interests, courts faced with a request for an injunction must show "particular regard for the public consequences" that employing such an "extraordinary remedy" will have. *Winter*, 129 S.Ct. at 376-377. The lower courts in this case gave no such special attention to the consequences of an injunction that could discourage the broader application of important advances in agricultural biotechnology.

1. Agricultural biotechnology creates numerous benefits for producers, consumers, and the environment.

As an initial matter, the lower courts seem to have ignored the public benefits of Roundup Ready alfalfa. Unlike conventional alfalfa, Roundup Ready alfalfa is genetically engineered to survive the appli-

cation of glyphosate, the active ingredient in the herbicide commercially known as Roundup® agricultural herbicide. As a consequence, a farmer who plants Roundup Ready alfalfa can use glyphosate to control weeds, in lieu of a more expensive, and possibly less effective, combination of other herbicides. See, *e.g.*, Pet. App. 122a; JA 596. By producing more alfalfa while spending less on chemicals for weed control, the Roundup Ready alfalfa farmer can realize potentially greater profits and yields. Not surprisingly, large numbers of alfalfa farmers were adopting the Roundup Ready variety when the district court issued its injunction.

Livestock farmers—the primary purchasers of alfalfa hay—also benefit from Roundup Ready alfalfa. The presence of weeds reduces the nutritional value of alfalfa hay. Pet. App. 126a-127a, 133a-134a. Thus, when farmers plant Roundup Ready alfalfa, they increase not only the quantity, but also the quality, of alfalfa hay available for purchase. In short, Roundup Ready alfalfa allows the production of more hay with fewer weeds—exactly what alfalfa hay consumers want.

In addition to providing benefits to alfalfa farmers and consumers, genetically engineered crops like Roundup Ready alfalfa provide significant benefits to the environment. As already mentioned, farmers who plant Roundup Ready alfalfa control weeds with glyphosate, as opposed to a variety of other herbicides. According to the US Environmental Protection Agency, glyphosate "has favorable human health, ecological and environmental fate properties." Pet. App. 195a-205a. So using glyphosate with Roundup Ready alfalfa can be especially beneficial when compared with some alternative plant and

herbicide combinations that farmers might otherwise have to use to control weeds in their fields.

The multiple benefits of Roundup Ready crops are just a few of the examples of agricultural biotechnology's potential. A 2004 study by the National Center for Food and Agricultural Policy found that genetically engineered crops increased annual yields by more than 5 billion pounds and increased annual farm incomes by $2 billion. See Sujatha Sankula & Edward Blumenthal, *Impacts on US Agriculture of Biotechnology-Derived Crops Planted in 2003—An Update of Eleven Case Studies* 92 (Oct. 2004), http://www.ncfap.org/documents/2004finalreport.pdf. At the same time, global pesticide applications fell 6 percent between 1996 and 2004, due in significant part to the development of pest-resistant biotechnology in plants. See Graham Brookes & Peter Barfoot, *GM Crops: The Global Socioeconomic and Environmental Impact—The First Nine Years 1996-2004* 10, PG Economics, Ltd., (2005), http://www.pgeconomics.co.uk/pdf/globalimpactstudyfinal.pdf. Herbicide-resistant crops have helped reduce the application of weed-controlling chemicals and facilitate the adoption of "no-till" farming methods that improve soil health and reduce erosion.

Astounding as these advances are, they amount to no more than a glimpse of what is possible. Agricultural biotechnology offers a way to help feed the world's population through safe, sustainable farming techniques that could raise the standard of living in rural communities around the globe. Beyond the benefits to the food supply and food suppliers, moreover, agricultural biotechnology can lead to the development of traits that facilitate the conversion of crops to biofuels or that may assist in delivering im-

portant health benefits. In short, agricultural biotechnology, and the crops derived from it, can provide real solutions to help feed, fuel, and heal the world.

2. The lower courts' injunction threatens to undermine important advances in agricultural biotechnology.

Experience has shown that, in spite of its numerous, proven benefits and long track record of safety, agricultural biotechnology is not well understood by the public at large. Notwithstanding consistent findings of safety from a variety of European scientific bodies, the European Union went twelve years without approving a genetically engineered crop for commercial planting. Six European countries, moreover, have effectively banned genetically engineered crops. See Paul Voosen, *Ghost of 'Frankenfood' Haunts Europe*, Greenwire (Oct. 21, 2009), http://www.nytimes.com/gwire/2009/10/21/21greenwire-ghost-of-frankenfood-haunts-europe-55309.html.

By approving an injunction without conducting the requisite balancing of harms, or considering available, relevant scientific evidence, the lower courts in this case may be charting a similar course for agricultural biotechnology in the United States. Already, another judge in the Northern District of California has ruled that the government's environmental review of genetically engineered Roundup Ready® sugar beets is insufficient. See *Center for Food Safety* v. *Vilsack*, No. C 08-00484, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009). That court now faces a request from the plaintiffs, including some of the same groups that are plaintiffs in this case, to enjoin the planting and sale of Roundup Ready sugar beets. To make matters worse, more than 90% of

sugar beet farmers have already switched to the genetically engineered variety, which was commercialized four years ago. An injunction like the one issued against the use of Roundup Ready alfalfa thus would cause a massive disruption for the overwhelming majority of sugar beet farmers, as well as for sugar processors and the communities in which they reside.

The ripple effect of the injunction here also could spread far beyond genetically engineered sugar beets. The government already has deregulated several other genetically engineered crops, including varieties of corn, cotton, papaya, and soy. And dozens of other products are currently going through the regulatory field-testing process. Decisions like the injunction against Roundup Ready alfalfa dramatically increase the degree of uncertainty surrounding the availability of these genetically engineered crops and can greatly slow the government's deregulation process.

The ongoing experience in Europe—more than a decade with little progress for genetically engineered crops—shows that, for an industry as young as agricultural biotechnology, the potential for setbacks is real. The United States has put in place a regulatory regime that for many years has been effectively reviewing and regulating genetically engineered crops, clearing 67 such crops for commercialization and allowing farmers and consumers in this country to reap the amazing benefits that they offer.[4] Now low-

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[4] The petition to deregulate Roundup Ready alfalfa is the 67th petition to deregulate a genetically engineered crop approved by the USDA since 1994, and the 11th petition granted specifically for a crop tolerant to the herbicide glyphosate, including soy

er courts have issued an injunction that threatens to undermine this successful system, without any serious consideration of the tremendous public benefits that could be lost. This is much more than a misapplication of the traditional four-factor equitable balancing test; it reflects a complete failure to comprehend the value of the relatively young, but vitally important, agricultural biotechnology industry.

II. ORDERING A NEW NEPA STUDY DOES NOT EXCUSE A COURT FROM WEIGHING EVIDENCE BEFORE ISSUING AN INJUNCTION.

Despite ostensibly finding that the plaintiffs would suffer irreparable injury without an injunction, and that the balance of hardships favored one, the district court did not hold an evidentiary hearing before enjoining the future planting and harvesting of Roundup Ready alfalfa. Pet. App. 67a-69a. As a result, "voluminous documentary submissions from both sides disputing, among other things, the likelihood of genetic contamination of non-Roundup Ready alfalfa fields" were never subject to cross-examination in open court. *Id.* at 17a. The rationale for not carefully considering this disputed evidence, as the court of appeals explained it, was that "an evidentiary hearing would require * * * the same type of extensive inquiry into environmental effects that the ordered EIS will require the government agency to perform." *Id.* at 18a. This line of reasoning effectively created a NEPA-specific rule under which relevant evidence can be disregarded when adjudicating a request for injunctive relief. Such a ca-

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(1994), cotton (1995), corn (1997), canola (1999), and sugar beet (2004). See http://www.aphis.usda.gov/brs/not_reg.html.

tegorical rule is inconsistent with this Court's precedent on multiple levels.

A. The Propriety Of Injunctive Relief Is A Separate Question From The Issues Addressed In A NEPA Study.

Precisely because the issuance of an injunction requires an equitable determination that entails a balancing of multiple competing interests, categorical rules are anathema to the process. As this Court has put it, "traditional equitable principles" exclude the use of "broad classifications" requiring or prohibiting injunctive relief. *eBay*, 547 U.S. at 392-393. In a NEPA case, as in any other, a court must impartially weigh the equities before issuing an injunction. See *Winter*, 129 S.Ct. at 376-377. By using the NEPA environmental-review process as an excuse to avoid scrutinizing evidence directly relevant to the equities, the decisions below would permit entry of an injunction in virtually every case in which NEPA is found to have been violated. That is precisely the kind of categorical rule that this Court rejected in *eBay*, and that the courts below should have eschewed.

Using NEPA review as a proxy for a finding of irreparable harm, as the lower courts did here, is both over-inclusive and under-inclusive. The potentially significant environmental impacts that an agency must catalogue pursuant to NEPA are readily segregable from the irreparable harms that factor into a court's injunctive-relief decision. Significant environmental impacts under NEPA can include anything from permanent alterations to the natural environment to smaller changes that can be completely mitigated in the ordinary course. The harm needed to invoke a court's injunctive powers, by contrast,

must be irremediable without an injunction. At the same time, while the proof sufficient for a finding of irreparable harm in an equitable setting varies depending on the purposes of the statute at issue, an EIS undertaken pursuant to NEPA is focused on harms to the environment and need only "indicate" those non-environmental factors that "are likely to be relevant and important to a decision." 40 C.F.R. § 1502.23.

More to the point, an agency's NEPA review is not an effort to make a decision based on a balance of hardships. The government's statutory responsibility in preparing an EIS is to document the potential environmental impacts of a proposed action, as well as of alternatives to that action. 42 U.S.C. § 4332(C). The EIS need not address the action's public or private benefits. If an agency conducting a NEPA review accurately reports the environmental effects, it may move ahead with its proposal, whether or not the proposal's benefits "outweigh" the environmental harms. Thus, when the courts below used the EIS that the agency would undertake pursuant to NEPA as a reason for not performing the traditional equitable balancing test, they ensured that the balancing test would never be performed. The result is an overbroad injunction that unfairly hurts the numerous innocent farmers who planned to grow Roundup Ready alfalfa, as well as the agricultural biotechnology industry and the public at large.

B. The Draft EIS Prepared By The Agency Is Not A Substitute For The Four-Factor Balancing Test.

When this case is argued, the district court's injunction against planting or selling Roundup Ready alfalfa will be more than three years old. The USDA

did not complete the Draft EIS ordered by the district court until November 2009. Public comments on the Draft EIS were due by March 3, 2010. When those comments are collected and reviewed, the USDA presumably will prepare a Final EIS and a Record of Decision concerning the petition to deregulate Roundup Ready alfalfa. That process is likely to take many months, particularly in light of the USDA's obligation to respond to what will almost certainly be a high volume of public comments. 40 C.F.R. § 1503.4(a). Ultimately, therefore, what the court of appeals described as an "interim" injunction intended to prevent duplication of the USDA's efforts (Pet. App. 18a) could remain in place for close to four years.

During the period in which alfalfa farmers and consumers have had to suffer from the effects of the overbroad injunction, the USDA has been doing much more work than the district court would have had to do if it had properly applied the traditional four-factor balancing test. Including appendices, the Draft EIS is more than 1,400 pages long, and it addresses numerous issues completely unrelated to the four factors. It is the height of inequity to issue an injunction far broader than what might otherwise be necessary on the ground that, over the next several years, the government planned to conduct a study that would address some of the same issues (along with many others that are completely irrelevant to the requisite balancing of interests). A district court is fully capable of weighing the sort of scientific evidence available in this case, or in any case that might involve an injunction against the use of agricultural biotechnology, and this Court's precedent on injunctions obliges it to do so.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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MARCH 2010

AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
MAR 8 - 2010
OFFICE OF THE CLERK

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO CO., ET AL.,
Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF AMICI CURIAE AMERICAN SUGARBEET GROWERS ASSOCIATION, U.S. BEET SUGAR ASSOCIATION, AND NATIONAL CORN GROWERS ASSOCIATION IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICI CURIAE[1]

The issues in this case have immense practical consequences for all segments of the economy related to agriculture. Because of their experience in the very aspects of agricultural regulation most relevant to this case, amici are uniquely well suited to address concerns that should inform this Court's analysis. Amici include representatives from a broad cross-section of two major agricultural crops that, for many years, have operated successfully within the regulatory framework that will be affected by the Court's resolution of the issues in this case. Collectively, amici include virtually all of the family farms that grow this nation's commercial sugarbeet crop, grower-owned cooperatives and processors that convert the vast majority of the sugarbeet crop into sugar, and hundreds of thousands of farmers involved in the nation's corn crop.

The American Sugarbeet Growers Association ("ASGA") is an organization of 10,000 sugarbeet growers, primarily family farmers, in all eleven sugarbeet-growing states: California, Colorado, Idaho, Michigan, Minnesota, Montana, Nebraska, North Dakota, Oregon, Washington, and Wyoming. ASGA's members grow all of the commercially

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[1] Letters of consent have been filed with the Clerk. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amici*, their members, or their counsel made a monetary contribution to the preparation or submission of this brief.

planted and harvested sugarbeets in the United States.

The U.S. Beet Sugar Association ("USBSA") is an organization of eight member companies that operate 22 processing factories in nine states. These firms produce refined sugar from sugarbeets grown by about 10,000 family farmers on approximately 1.3 million acres in the eleven sugarbeet-growing states. ASGA and USBSA have participated as amici in prior cases that affect the vital economic interests of their members.

The National Corn Growers Association ("NCGA") represents 35,000 dues-paying corn farmers nationwide and the interests of more than 300,000 growers who contribute through corn checkoff programs in their states. NCGA and its 48 affiliated state associations and checkoff organizations work together to create and increase opportunities for their members and their industry.

Based upon their extensive practical experience with the technology and regulatory regimen at issue in this case, amici are in a position to address the important agricultural, economic, and environmental issues presented. Amici's interest in these issues is not hypothetical or theoretical. A group of plaintiffs in ongoing litigation is currently seeking to extend the erroneous standards in the decision below to the national sugarbeet crop. *See Center for Food Safety v. Conner*, No. 3:08-cv-00484-JSW (N.D. Cal.). In ruling on summary judgment in that case, the district court cited the Ninth Circuit's decision below in *Geertson* extensively on every

significant point in its analysis. Accordingly, the issues in this case have already have had an impact on other key segments of the agricultural industry.

This Court's decision will reverberate throughout the economy, affecting a panoply of crops and industries. Considerations of the real-world impact of the issues in this case should materially assist the Court's analysis.

BACKGROUND OF FEDERAL REGULATION OF MODIFIED CROPS

A. Agricultural Background

Alfalfa is but one of some 75 genetically-modified crops that the United States Department of Agriculture ("USDA") has de-regulated over the past two decades. *See* U.S. Department of Agriculture, APHIS, Petitions of Nonregulated Status Granted or Pending by APHIS as of February 2, 2010, http://www.aphis.usda.gov/brs/not_reg.html (last visited Feb. 23, 2010). In each instance, the USDA's Animal and Plant Health Inspection Service ("APHIS") concluded its analysis by issuing an Environmental Assessment ("EA"). *Id.* Based on its intimate familiarity with the underlying science and agronomics, USDA has consistently applied the appropriate standards to its analysis.

With respect to Roundup Ready sugarbeets, USDA specifically addressed all pertinent questions relating to gene flow concerns for seed production of this important crop in the United States. About 50-55% of all domestic sugar production is derived from

sugarbeets. *See* http://cropwatch.unl.edu/web/sugarbeets/sugarbeet_history (last visited 2-18-10).

In the eleven states that produce sugarbeets, weed control poses one of the most pressing, time-consuming, and expensive difficulties in harvesting the crops. *See* Abram, *Roundup Ready Crops Prove to Be a Hit in USA*, FARMERS WEEKLY (Feb. 7, 2009), at 61. Prior to recent technological developments, a typical planting season required about 15 separate passes with a tractor, including as many as six passes to spray a variety of weed killers, capped with a final pass by farmworkers to hand-hoe the fields. *See* Jenkins, *Biotech Beet-Down*, HIGH COUNTRY NEWS at 6 (Oct. 12, 2009) ("In the old days . . . it was just a real fight to get the beets out of the weeds"). Even when applied properly, traditional chemicals could damage sugarbeet plants and reduce crop yield. Additional environmental benefits exist with Roundup Ready sugarbeets as opposed to conventional ones, in that no post-planting tillage is required with Roundup Ready sugarbeets, which limits the potential for sediment runoff to streams and other water bodies.

About ten years ago, Monsanto developed sugarbeets that were genetically modified to be compatible with the herbicide glyphosate (*i.e.*, Monsanto's "Roundup" weed killer product). *See id.* Because these "Roundup Ready" sugarbeets provided such enormous benefits for farmers, they rapidly became the industry standard. Farmers no longer had to make four or five applications of conventional herbicides, resulting in significant savings on fuel, water, and labor. Furthermore, Roundup was

indisputably less toxic than some conventional herbicides previously used by sugarbeet farmers. *See* Lydersen, *Monsanto Beets Down Opposition*, IN THESE TIMES (Nov. 21, 2008) (quoting attorney for plaintiff Center for Food Safety as acknowledging that "Roundup is a less toxic alternative than a lot of the herbicides").

Production of these genetically modified sugarbeets was initially regulated pending further study. *See* Jenkins, *Biotech Beet-Down*, HIGH COUNTRY NEWS at 6. Following comprehensive experiments, testing, evaluation, and review of a 4,816-page administrative record, USDA and APHIS concluded in early 2005 to deregulate Roundup Ready sugarbeets as a crop. As set forth in an EA, the government found that they were "just as safe" as conventional sugarbeets, and would have "no significant impact on the human environment."[2] The EA further noted that Roundup Ready sugarbeets are "unlikely to have any adverse impact on agricultural practices on raw or processed agricultural commodities in the U.S.," and "will not have significant adverse impacts on organisms beneficial to plants or agriculture, other non-target organisms, or threatened or endangered species." Based upon a full assessment of the scientific record, the EA concluded that preparation of an Environmental Impact Statement ("EIS") was not necessary.

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[2] The USDA/APHIS's February 2005 EA may be accessed at: http://www.aphis.usda.gov/brs/aphisdocs2/03_32301p_com.pdf

The USDA/APHIS's 2005 decision effectively cleared Roundup Ready sugarbeets for commercial planning. *See* Abram, *Roundup Ready Crops Prove to Be a Hit in USA*, FARMERS WEEKLY, at 60. Roundup Ready sugarbeets were first planted commercially in 2006. In 2008, approximately half the domestic sugarbeets were Roundup Ready. *See* Jenkins, *Biotech Beet-Down*, HIGH COUNTRY NEWS at 7. By the end of 2009, the number was 95%. *Id.* This should not be surprising, since sugar from Roundup Ready beets is identical to sugar from other sugarbeets and from sugar cane.

Even before USDA's deregulatory decisions with respect to sugarbeets in 2005 and alfalfa later the same year, farmers of many other crops had experienced similar success with the introduction of Roundup Ready seeds. Accordingly, USDA and APHIS had the benefit of extensive data regarding the safety and environmental history of glyphosate tolerant seeds. For example, Roundup Ready corn has been commercially available since 1998. Pet. App. 168a. Today, more than half of our domestic corn production is derived from Roundup Ready corn. *See id.* at 258a-59a. The first genetically modified seeds—soybeans—were approved for deregulation in 1994. *See* http://www.aphis.usda.gov/brs/aphisdocs2/93_25801p_com.pdf.

B. Regulatory and Litigation Background

Subsequent to USDA deregulation, Roundup Ready seeds for a multitude of crops have proven the wisdom of the regulatory decisions. But, following the decisions below in this case, litigants tried to

bootstrap the rulings on alfalfa in *Geertson* to enjoin the planting of other crops with no evidence of environmental harm. Sugarbeet farmers and processors have been victimized by this pernicious trend. Following several successful planting seasons in which growers, processors, and consumers enjoyed the environmental and economic benefits of Roundup Ready sugarbeets, a group of plaintiffs filed suit to challenge USDA's issuance of an EA rather than an EIS. That procedural challenge did not commence until after the district court in the alfalfa case had granted an injunction.

The Ninth Circuit's later affirmance in *Geertson* had a pivotal, deleterious impact on the sugarbeet litigation. In September 2009, summary judgment in the sugarbeet case was granted on the question whether the USDA complied with the National Environmental Policy Act ("NEPA"). *See Ctr. for Food Safety v. Vilsack*, 2009 U.S. Dist. LEXIS 86343 (N.D. Cal. Sept. 21, 2009). In finding a procedural violation of NEPA in APHIS's conclusion that preparation of an EIS was unnecessary, the district court in the sugarbeet case was influenced heavily by both the district court and Ninth Circuit opinions from the alfalfa case, and cited both alfalfa opinions extensively. *See id.* at *6, **25-30.

Seeking to expand their success in *Geertson* to other agricultural crops, the plaintiffs in the sugarbeet litigation then moved for a preliminary injunction to prohibit the planting of Roundup Ready sugarbeets while the USDA completes a full EIS. In belatedly seeking such relief (four years after Roundup Ready sugarbeets entered the market), the

plaintiffs in the sugarbeet litigation are relying on a presumption of irreparable harm, even though there is no evidence of actual adverse environmental impact. *See Center for Food Safety*, No. 3:08-cv-00484-JSW, Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, D.E. 194-1 at 10-12, (filed 1/19/10). Moreover, they contend that an evidentiary hearing is not necessary for airing and resolution of disputed facts. *See id.*, Supplemental Joint Case Management Statement, D.E. 173 at 7-8 (filed 11/25/09). These positions are asserted under the purported authority of the Ninth Circuit's decision in *Geertson*.

If an injunction were to issue, then sugarbeet growers would have to scramble for whatever alternative seed supplies remain in stock (which will not be much). *See* Abram, *Roundup Ready Crops Prove to Be a Hit in USA*, FARMERS WEEKLY, at 60 ("Losing [Roundup Ready] beet would be devastating to growers"). They would have to return to other herbicides and try to find work crews to hoe their fields again, a practice countless growers sensibly abandoned after switching to Roundup Ready sugarbeet seed. Moreover, an injunction would wreak havoc on domestic sugar supply and price, "thereby decimating the entire sugar beet industry and almost half of the nation's domestic sugar supply for multiple years." *See Center for Food Safety*, No. 3:08-cv-00484-JSW, Federal Defendant's Opposition to Plaintiffs' Motion for a Preliminary Injunction, D.E. 272 at 1, (filed 2/12/10).

SUMMARY OF ARGUMENT

Unless it is reversed, the decision below threatens great mischief in the application of settled legal principles to critically important segments of the economy. There is no merit to the proposition that sound decisions by expert regulatory agencies – which have withstood the test of time in actual practice – should be swept aside on the basis of a presumption of irreparable harm. It is even worse that farmers and processors whose livelihoods will be victimized by that presumption should be denied an evidentiary hearing.

The circumstances of this case and the follow-on sugarbeet litigation now pending in the Northern District of California illustrate precisely why the Ninth Circuit's presumption of irreparable harm is altogether misplaced. Neither precedent nor principle supports the decision below. It is, moreover, bad economic and environmental policy.

Rather than apply the traditional four-factor analysis for injunctive relief, the Ninth Circuit has persisted in employing a presumption of irreparable harm that cannot be reconciled with this Court's decisions. *Winter v. NRDC*, 129 S.Ct. 365 (2008) is the most recent example in a long line of consistent cases that make the Ninth Circuit's outlier approach wholly untenable.

Indeed, when the stated pedigree of the Ninth Circuit's view is examined, it turns out to be based on a misperception of prior authorities. Some 35

years ago, the D. C. Circuit, in *Jones v. D.C. Redevelopment Land Agency*, 499 F.2d 502 (D.C. Cir. 1974) mistakenly expanded on an earlier Ninth Circuit opinion to expound the proposition that harm necessarily flowed from statutory violations. The earlier Ninth Circuit case, which turned entirely on its unique facts, had not created any such broad, inflexible rule. But, armed with *Jones*, the Ninth Circuit picked up the ball and ran with it. And it has been running in the wrong direction ever since.

Where, as in this case, important legal issues intersect with vital economic and environmental interests of the United States, this Court should ensure that the traditional limitation of injunctions to extraordinary cases should be strictly enforced. If well reasoned agency proposals for remedying a NEPA vioaltion are to be nullified, it should only be where the challenging party has satisfied its heavy burden through the presentation of sufficient evidence. A presumption of irreparable harm is no substitute for evidence. The ongoing sugarbeet litigation offers a compelling example of how the Ninth Circuit's presumption has enormous potential for deleterious application. In contrast to the wholly conjectural harm that plaintiffs seek to cloak in a presumption, the harm of a threatened injunction to the farmers and processors of sugarbeets is palpable, concrete and massive. That scenario should not be repeated for the many other crops that have benefited for years from modified seeds without producing any of the hypothetical harm alleged in this case and in the sugarbeet litigation.

Equally as disturbing as the presumption of irreparable harm is the Ninth Circuit's error in permitting an injunction to issue without an evidentiary hearing. Hearings at which evidence is subjected to the truth-distilling cauldron of cross-examination form the cornerstone of our legal system. To unleash the economic chaos of an injunction in the circumstances presented here – without affording an opportunity to confront, rebut and demolish the baseless challenge at an evidentiary hearing – should be unthinkable.

ARGUMENT

I. THE OPINION BELOW ERRONEOUSLY RELAXED THE STANDARD FOR INJUNCTIVE RELIEF IN NEPA CASES

A. Injunctions Should Issue in Only Most Extraordinary Cases

As this Court held last Term, an "injunction is an extraordinary remedy never awarded as of right." *Winter*, 129 S.Ct. at 376 (quoting *Munaf v. Geren*, 128 S.Ct. 2207, 2219 (2008)). Generally, an injunction should issue only when the party seeking equitable relief satisfies the traditional four-part test with evidence—not presumptions. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). These factors are "(1) that [plaintiff] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is

warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.* The four traditional factors have been consistently applied in the environmental context. *See* 61B AM JUR. 2D *Pollution Control* §139 (2001) (citing numerous lower court decisions).

In further recognition that presumptions have no place in the injunction calculus in cases involving statutory violations, this Court has long viewed the authority to grant equitable remedies as a power that should be exercised on a case-by-case basis as the facts warrant. *See, e.g., Hecht Co. v. Bowles,* 321 U.S. 321, 329 (1944). Courts "mould each decree to the necessities of the particular case" (*id.*), balancing "the conveniences of the parties and possible injuries to them according as they may be affected by the granting or withholding of the injunction." *Yakus v. United States,* 321 U.S. 414, 440 (1944).

B. Irreparable Harm Cannot Be Presumed Upon a Showing of a Procedural Violation of a Statute

"[T]he basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies." *Weinberger v. Romero-Barcelo,* 456 U.S. 305, 312 (1982) (citing several precedents); *see also Samuels v. Mackell,* 401 U.S. 66, 68-69 (1971) (federal injunction to enjoin state prosecution requires that irreparable injury be "show[n] in the record," rather than "alleged"). In contrast to this Court's clear directives, the Ninth Circuit held in this case that irreparable harm can be presumed in NEPA cases upon the showing of a

procedural NEPA violation.[3] In the court of appeals' view, the irreparable harm results not from actual injury to the environment, but from the supposed failure to comply with NEPA's procedural requirements. Such a position cannot be reconciled with this Court's precedents.

This Court has never presumed irreparable injury from statutory violations.[4] If the Ninth

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[3] In opposing the petition for certiorari, respondents disputed that the Ninth Circuit presumed irreparable harm. *See* Geertson Seed Farms, *et al.*, Opp. Cert. at 16-18. That is an insupportably strained reading of the decision below. But even if this particular opinion could be parsed that way, the Ninth Circuit has in the past expressly presumed irreparable harm upon a finding of noncompliance with NEPA. *See, e.g., Sierra Club v. Bosworth*, 510 F.3d 1016, 1034 (9th Cir. 2007) ("in the NEPA context, irreparable injury flows from the failure to evaluate the environmental impact of a major federal action; quoting *High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 642 (9th Cir. 2004)); *Nat. Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 737-38 & n.18 (9th Cir. 2001) (similar) The sugarbeet plaintiffs are currently asserting this very argument and relying on these Ninth Circuit decisions in their attempt to leverage precisely this presumption into an industry-crippling injunction. *See Center for Food Safety*, No. 3:08-cv-00484-JSW, Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, D.E. 194-1 at 10-12. (filed 1/19/10) ("The Ninth Circuit has emphasized that harm occurs whenever actions are allowed to proceed before the NEPA process is completed, in addition to the specific harm to the environment"). Moreover, in their initial papers requesting an injunction, the sugarbeet plaintiffs relied heavily on the Ninth Circuit's decision in Geertson without mentioning that certiorari had already been granted. *See id.* at 4, 16, 18.

[4] Some of this Court's opinions suggest that a presumption of irreparable harm may be appropriate in the context of

Circuit's view were accepted, then "the courts would presume irreparable harm in deciding every preliminary injunction motion made in cases brought under federal statutes. [But that] is certainly not the law." *King v. Pine Plains Cent. Sch. Dist.*, 923 F. Supp. 541, 546 (S.D.N.Y. 1996).

In *Winter*, this Court recently considered a request for an injunction in a NEPA case, and applied the traditional test for injunctive relief. In that case, the U.S. Navy had prepared an EA, but not an EIS, concerning the effects of "mid-frequency active" sonar on marine mammals. 129 S.Ct. at 370. This Court reversed the Ninth Circuit's holding that a preliminary injunction may be granted where the plaintiff had shown only the "possibility" of irreparable injury. *Id.* at 375. Such a standard was too lenient. Accordingly, this Court held that in the context of a preliminary injunction, a plaintiff must establish that irreparable injury is not just a "possibility," but is "likely." *Id.*

Winter thus erased any doubt whether a "NEPA exception" applies to the traditional four-part test for injunctive relief. It does not.[5]

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injunctive relief for *constitutional* violations. *See, e.g., Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion); *Dombrowski v. Pfister*, 380 U.S. 479, 486-87 (1965). But there is neither precedent nor rational support for a presumption in any other context.

[5] *See also San Luis Valley Ecosystem Council v. United States Fish and Wildlife Serv.* 657 F. Supp.2d 1233, 1240 (D. Colo. 2009) (*Winter* held "that a presumption of irreparable environmental harm is not appropriate" in NEPA cases); *Sierra*

Moreover, *Winter* is well-grounded in this Court's precedents. Previously, this Court had rejected the proposition that violation of a federal procedural mandate is sufficient to bypass the traditional need to show irreparable harm. *See Sampson v. Murray*, 415 U.S. 61 (1974). *Sampson* involved a claim for an injunction precluding the firing of a probationary government employee whose only substantive claim was that her employer had violated federal procedural Civil Service regulations in effecting her discharge. The district court had granted a preliminary injunction. But this Court reversed, holding that the grant of injunctive relief was erroneous without a conclusion by the district court that irreparable injury existed. *Id.* at 88.[6]

The same standard applies in the environmental context. For example, *Weinberger* involved an attempt by the governor of Puerto Rico

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Club v. U.S. Forest Serv., 593 F. Supp. 2d 1306, 1323 (N.D. Ga. 2008) ("there is no presumption entitling plaintiffs to automatic injunctive relief merely because there has been a NEPA violation"; citing *Winter*); Mandelker, NEPA LAW AND LITIGATION §4:56.1 at 4-180 (2009) (*Winter* "will make it harder for environmental plaintiffs to secure preliminary injunctive relief" in NEPA cases).

[6] After *Sampson*, lower courts that had previously presumed irreparable harm to parties seeking injunctions in federal employment cases reversed themselves and required a showing of irreparable harm. *Compare, e.g., United States v. Hayes Int'l Corp.*, 415 F 2d 1038, 1045 (5th Cir. 1969) (presuming irreparable harm in Title VII cases); *with Parks v. Dunlop*, 517 F.2d 785, 786-87 (5th Cir. 1975) (requiring a showing of irreparable harm).

to enjoin the U.S. Navy from using weapons training off the coast of Puerto Rico, arguing that such activities violated the Federal Water Pollution Control Act because the Navy had not obtained the relevant permits. *See* 456 U.S. at 310-11. The First Circuit held that there was an "absolute statutory obligation" to stop the activities until the permit was "granted." *See id.*

This Court reversed in an opinion emphasizing that the traditional balancing factors "applicable to cases in which injunctions are sought in the federal courts reflect a practice with a background of several hundred years of history, a practice of which Congress is assuredly well aware." *Id.* at 313 (quotation omitted). As this Court concluded, "unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." *Id.* at 305 (citation omitted).

Five years later, a similar situation arose when Alaskan native villages sought to enjoin the Secretary of the Interior's sale of oil and gas leases for federally-owned lands in the outer continental shelf of Alaska. *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531 (1987). Plaintiffs alleged a failure to comply with the federal Alaska National Interest Lands Conservation Act, because the Secretary "did not have the policy precepts [of the act] in mind at the time of the evaluation." *Id.* at 540.

Much as it did in the instant case, the Ninth Circuit held that "[i]rreparable damage is presumed when an agency fails to evaluate thoroughly the environmental impact of a proposed action . . . injunctive relief is the appropriate remedy for a violation of an environmental statute absent rare or unusual circumstances." *Id.* at 541 (quoting Ninth Circuit decision). This Court again reversed, holding that all four factors (including irreparable harm) must be demonstrated before an injunction could issue. *See id.* at 544-45; *see also Del. Dep't of Natural Res. & Envtl. Control v. United States Army Corps of Engineers*, 2010 U.S. Dist. LEXIS 6398, at *40 (D. Del. Jan. 21, 2010) ("environmental harm must be substantiated, as it would be contrary to traditional equitable principles to presume irreparable injury from an agency's alleged failure to evaluate thoroughly the environmental impact of a proposed action"; quoting *Amoco*).

Although neither *Weinberger* nor *Amoco* arose under NEPA, numerous lower courts have correctly interpreted those precedents as fully applicable to NEPA cases.[7] Moreover, any possible argument that

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[7] *See, e.g., Huntington v. Marsh*, 884 F.2d 648, 651-53 (2d Cir. 1989) (holding in NEPA case that "injunctive relief does not follow automatically upon a finding of statutory violations, including environmental violations;" citing *Weinberger* and *Amoco*); *Wisconsin v. Weinberger*, 745 F.2d 412, 425 (7th Cir. 1984) (holding in NEPA case that an injunction "is not a remedy which issues as of course;" citing *Weinberger*); *Sierra Club*, 593 F. Supp. 2d at 1324 & n.25 (noting that several courts have applied *Weinberger* and *Amoco* in NEPA context); *County of Los Alamos v. U.S. DOE*, 2006 U.S. Dist. LEXIS 27262, at *22 (D.N.M. Jan. 13, 2006) ("invocation of an environmental

Weinberger and *Amoco* are inapplicable to NEPA cases cannot be reconciled with *Winter*.

Nor can the Ninth Circuit's view be reconciled with the standard articulated in denying an application for a stay in a NEPA case:

> [The protections of NEPA] *should not lead courts to exercise equitable powers loosely or casually whenever a claim of "environmental damage" is asserted.* The world must go on and new environmental legislation must be carefully meshed with more traditional patterns of federal regulation.

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statute such as NEPA does not alter these traditional rules for injunctive relief, and there is no presumption that an injunction automatically follows if there is any violation of an environmental statute;" citing *Weinberger* and *Amoco*); *Montrose Parkway Alternatives Coalition v. U.S. Army Corps of Engineers*, 405 F. Supp.2d 587, 599 (D. Md. 2005) ("presuming irreparable harm in all environmental cases would contravene traditional equitable principles;" citing *Amoco*); *Sierra Club v. U.S. Fish and Wildlife Serv.*, 235 F Supp.2d 1109, 1139 (D. Colo. 2002) ("Irreparable environmental injury may not be presumed from an agency's failure to appropriately evaluate environmental impacts in an EIS;" citing *Amoco*); *Hirt v. Richardson*, 127 F. Supp.2d 833, 845 (W.D. Mich. 1999) ("While [plaintiffs] logically imply that the violation of NEPA inherently creates an irreparable injury, because the inadequately informed decision has already been made, the United States Supreme Court has made it clear that violations of procedural environmental statutes do not mandate the issuance of an injunction, and that plaintiffs must still show some tangible irreparable environmental injury").

Aberdeen & Rockfish R. Co. v. SCRAP, 409 U.S. 1207, 1217-18 (1972) (Burger, C.J., in chambers) (emphasis added). As this Court's decisions consistently explain, there is no justification for bypassing traditional equitable principles merely because the statute at issue involves the environment. The cornerstone of justifiable injunctive relief is a solid evidentiary basis to support the extraordinary remedy.

C. The Presumption of Irreparable Harm for NEPA Violations is Premised Upon Faulty Legal Foundations

In any event, the principle that irreparable harm may be presumed upon a showing of NEPA violations rests upon an especially weak foundation. Upon examination, it is evident that the Ninth Circuit's view is built on layers of misperceptions of prior cases. The first time a Ninth Circuit panel employed a presumption of irreparable harm was in *Friends of the Earth, Inc. v. Coleman*, 518 F.2d 323, 330 (9th Cir. 1975). For this novel view, *Friends of the Earth* cited the D.C. Circuit's opinion in *Jones v. D.C. Redevelopment Land Agency*, 499 F.2d 502, 512 (D.C. Cir. 1974), and an unpublished district court decision that also cited *Jones*. *See* 518 F.2d at 330 (citing *Jones* and *City of Boston v. Brinegar*, 6 E.R.C. 1961, 1965 (D. Mass. 1974)).

But *Jones* did not cite any statutory language or legislative history for its conclusion that harm may necessarily flow from a failure to comply with NEPA. Rather, it referred—quite mistakenly—to an earlier Ninth Circuit opinion for its determination

that a procedural NEPA infraction automatically results in harm. *See* 499 F.2d at 512 (citing *Lathan v. Volpe*, 455 F.2d 1111 (9th Cir. 1971)).

In that citation, *Jones* was incorrect. *Lathan* never enunciated a rule that harm, much less irreparable harm, is always presumed following a NEPA violation. The plaintiffs in *Lathan* were property owners who sought an injunction against further acquisitions of property by highway officials pending, *inter alia*, the preparation of an EIS in accordance with NEPA. The *Lathan* plaintiffs contended—and the government conceded—that absent an injunction, the plaintiffs would be unable to sell their property to anyone other than the government. *See* 455 F.2d at 1116. The Ninth Circuit declined to require the plaintiffs to prove the usual elements for an injunction because the irreparable harm to the plaintiffs was obvious in these circumstances. *See id.* ("The longer the delay in applying NEPA, the more the neighborhood will have deteriorated and the less will be the chance to protect the city and its people from the environmentally detrimental effects of this project"). But the Ninth Circuit emphasized that the circumstances of the case were "exceptional " and the case was "one of those comparatively rare cases in which, unless the plaintiffs receive *now* whatever relief they are entitled to, there is danger that it will be of little or no value to them or to anyone else when finally obtained." *Id.* (emphasis in original).

In short, *Lathan* was an extraordinary case involving extraordinary facts. By citing *Lathan* as supporting a generalized proposition for NEPA cases,

the D.C. Circuit in *Jones* erroneously turned *Lathan*'s fact-based conclusion into an ironclad rule of law. Later cases such as *Friends of the Earth* amplified and perpetuated *Jones'* mistake.[8]

At the end of the day, the Ninth Circuit's view lacks doctrinal and precedential support. This Court should put this erroneous proposition to rest. *See Amoco*, 480 U.S. at 544-45.

D. Plaintiffs Who Seek Injunctions in NEPA Cases Must Satisfy the Traditional Four-Part Test

This Court's precedents make clear that, absent constitutional violations, the usual standard for showing "likely" irreparable harm is required for injunctions. *See Winter*, 129 S. Ct. at 375-76. Moreover, the "likely" irreparable harm should be tangible, or at least imminent. *See, e.g., Weinberger*, 456 U.S. at 310 (citing *TVA v. Hill*, 437 U.S. 153 (1978)); *see also Samuels*, 401 U.S. at 68-69 (irreparable injury must be "show[n] on the record," rather than "alleged"); *N.Y. v. Nuclear Regulatory Com.*, 550 F.2d 745, 754 (2d Cir. 1977) (denying NEPA injunction when federal action was not "certain to produce the cataclysmic consequences appellant fears will ensue"). And the harm must be

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[8] In contrast, other courts have refused to read *Lathan* as obviating the need to show irreparable harm, correctly noting that it was an "exceptional" case. *See, e.g., Essex Cty. Preservation Ass'n v. Campbell*, 536 F.2d 956, 962 (1st Cir. 1986); *King*, 923 F. Supp. at 546-47; *Alaska Conservation Society v. Brinegar*, 3 Envtl. L. Rep. 20744, 20744 (D. Alaska 1973).

to the environment directly, rather than a vague and amorphous harm to the public for failure to comply with NEPA's procedural requirements. *See Amoco*, 480 U.S. at 543.

As this Court held last Term, the traditional test of balancing equities is mandatory in NEPA cases. *See Winter*, 129 S.Ct. at 376-81 (even assuming irreparable harm, district court erred in not balancing equities in NEPA case when it issued injunction); *cf. Strycker's Bay Neighborhood Council, Inc. v. Karlen*, 444 U.S. 223, 228 n.2 (1980) (NEPA does not require agency "to elevate environmental concerns over other, admittedly legitimate, considerations").

The sugarbeet litigation illustrates the necessity of applying the traditional balancing test in NEPA cases. Plaintiffs in the sugarbeet litigation are seeking an injunction that would have far-reaching consequences in rural communities in 11 states where sugarbeets are grown. In just four years, domestic commercial plantings of Roundup Ready sugarbeets have come to comprise 95% of the United States crop in 2009. This has been by far the fastest adoption of biotech of any crop in agricultural history. *See* Abram, *Roundup Ready Crops Prove to Be a Hit in USA*, FARMERS WEEKLY, at 61. Utilization of Roundup Ready beets greatly improves weed control. Fuel, water, and labor costs are reduced because fewer applications of harsh herbicides are needed. *See* pages 4-5, *supra*.

A ban on Roundup Ready sugarbeets would result in severe seed shortages in some areas and

billions of dollars in losses—lost crops, lost jobs, lost sales of new farm equipment, lost value of existing specialized sugarbeet farm equipment that would be obsolete because its only use is for sugarbeet crops, lost tax revenue, and the closures of grower-owned processing plants that would never re-open. If beet farmers were forced to switch to other crops (such as potatoes or onions), that dislocation would, in turn, depress prices in states that already service those crops, leading to additional adverse ripple effects (more job losses, etc.) to the farming economy. And needless to say, halting cultivation of 95% of all sugarbeets would result in a severe domestic sugar shortage and a staggering increase of domestic sugar prices at the grocery store and throughout the food producing industry. *See Center for Food Safety*, No. 3:08-cv-00484-JSW, Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, D.E. 272 at 17-20 (filed 2/12/10) (citing declaration of USDA's Daniel Colacicco at ¶¶ 15-28).

Congress has not provided any indication that it intended such disruption. There is, accordingly, no basis for courts in NEPA cases to bypass any of the traditional rules for injunctions. *Cf. Weinberger*, 456 U.S. at 313.

II. THE COURT OF APPEALS ERRED IN AFFIRMING THE LOWER COURT'S REFUSAL TO CONDUCT AN EVIDENTIARY HEARING

The court of appeals compounded its error by upholding the district court's refusal to conduct an evidentiary hearing justifying the injunction.

Effectively, the Ninth Circuit endorsed a rule that 1) presumed irreparable harm upon a showing of a statutory procedural violation and 2) denied petitioners an effective opportunity to rebut and/or disprove the presumption through an evidentiary hearing. This Court should reverse.

For two centuries, this Court has decreed that injunctions may not issue without giving all parties an opportunity to be heard. *See Marshall v. Beverly*, 18 U.S. 313, 316 (1820). Lower courts assiduously apply the "cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings," because "[a]ny other course would be contrary 'to the spirit which imbues our judicial tribunals prohibiting decision without a hearing.'" *United States v. Microsoft*, 253 F.3d 34, 101 (D.C. Cir. 2001) (en banc) (quoting *Sims v. Greene*, 161 F.2d 87, 88 (3d Cir. 1947)); *see also In re Rationis Enterprises, Inc. of Panama*, 261 F.3d 264, 269 (2d Cir. 2001) (same and citing numerous authorities). As the leading commentators of federal procedure explain, where pivotal facts are disputed in an injunction proceeding, "[t]he court should insist, as it did here, on the presentation of oral testimony which may be subjected to the test of cross-examination." 11A Wright, Miller & Kane, FEDERAL PRACTICE AND PROCEDURE *Civil* (2d) §2949 at 224 (1995) (quoting *Industrial Electronics Corp. v. Cline*, 330 F.2d 480, 483 (3d Cir. 1964)).

NEPA cases are not exempt from this "cardinal principle." *Cf. Aberdeen & Rockfish*, 409 U.S. at 1217-18 (Burger, C.J., in chambers) (courts

should not depart from traditional equitable standards in environmental cases). Indeed, "[t]he use of evidentiary trials and hearings, expert witnesses, and expert affidavits and other evidentiary documents challenging agencies' environmental reviews has become commonplace in NEPA cases[.]" French, *Judicial Review of the Administrative Record in NEPA Litigation*, 81 CALIF. L. REV. 929, 950-53 (1993) (citing statistics and cases).

The follow-on sugarbeet litigation offers a clear perspective on the need for evidentiary hearings in such cases. Brought in the same court, by some of the same plaintiffs, and the same trial counsel as the present case, the sugarbeet plaintiffs' claims of irreparable injury are largely based upon the theoretical possibility that Roundup Ready sugarbeets would result in "cross-pollination" to other nearby crops in the Willamette (Oregon) Valley. But Roundup Ready sugarbeets have been grown for seed in the Willamette Valley for years without any such cross-pollination whatsoever. Discovery in that litigation has further revealed that even if any such conjectural cross-pollination were to occur, it would be of a very limited nature and fully reparable. Given the profound impact that an injunction would necessarily entail (*see supra* at 8), it is of paramount importance that an evidentiary hearing be conducted in the sugarbeet case, as in the alfalfa case, so that the plaintiffs' allegations of injury can be fully debunked.

The sugarbeet plaintiffs also cite alleged cross-pollination in Europe, where conditions for growing

sugarbeets are altogether different. An evidentiary hearing would provide the needed opportunity to thoroughly refute the unfounded charges of cross-pollination.

If any further justification for an evidentiary hearing were required, the record in *Geertson* more than suffices. In particular, one of the district court's stated rationales for denying an evidentiary hearing should set off alarm bells. The district court below suggested that the subject matter was too complex for an evidentiary hearing: "I feel particularly ill suited to" engage "in the balancing of all these different factors and coming to particular conclusions." Pet. App. 417a.

Federal judges preside over cases involving all types of "arcane matters in such areas as patent, admiralty, tax, antitrust, and bankruptcy law, on a daily basis." *Parisi v. Davidson*, 405 U.S. 34, 53 (1972) (Douglas, J., concurring). Where a subject matter is complex or where a federal judge feels "particularly ill-suited" to making a decision on the merits, there is all the more reason for a full evidentiary hearing. Especially in these circumstances, to enjoin an expert agency's determination on the basis of presumptions and evidence untested by cross-examination is dangerous folly. This Court should reject the Ninth Circuit's approach and restore sound policy and law in this critical area.

CONCLUSION

The judgment should be reversed.

Respectfully submitted.

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March 8, 2010

AMICUS CURIAE BRIEF

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF AMICUS CURIAE ARKANSAS RICE GROWERS ASSOCIATION, RICE PRODUCERS OF CALIFORNIA, NEW ENGLAND FARMERS UNION, COMMUNITY ALLIANCE WITH FAMILY FARMERS, FEDCO SEEDS, INC., NATIONAL FARMERS UNION OF CANADA, GENETICS INTERNATIONAL, ECKENBERG FARMS, INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENTS, INTERNATIONAL COMMISSION ON THE FUTURE OF FOOD AND AGRICULTURE IN SUPPORT OF RESPONDENTS

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INTERESTS OF AMICI CURIAE[1]

Amici Curiae ("*Amici*") are farmers and growers who grow conventional (not genetically engineered) rice, alfalfa, hay and other products for domestic sale and export. *Amici* are deeply concerned that if genetically engineered ("transgenic") alfalfa (also known as Roundup Ready Alfalfa ("RRA")) is unleashed upon the environment without adequate safeguards, and prior to the completion of environmental review, it is highly likely that genetically engineered alfalfa will contaminate conventional alfalfa crops through open pollination (e.g., bees) and other routes, causing irreparable harm to the environment.

Genetically engineered ("GE") crops have already contaminated conventional crops, resulting in damages of over a billion dollars to the rice trade, and ruinous results to many of *Amici*'s export operations. Many major trade partners, including Japan, Korea, the European Union and many Middle Eastern countries refuse to accept genetically engineered crops. While some farmers may debate the benefits and detriments of genetically engineered crops, all farmers agree that they must respond to the demands of their markets. When genetically engineered material un

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[1] Letters of consent have been filed with the Clerk allowing the filing of this amicus brief. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part, and no person or entity other than *amici*, their members, or their counsel made a monetary contribution to the preparation or submission of this brief. Counsel for *Amici* are members of the bar of this Court.

expectedly contaminates the food supply, market consequences for farmers are severe.

Amici include the Arkansas Rice Growers Association (ARGA), the Rice Producers of California, the New England Farmers Union, the Community Alliance with Family Farmers, Fedco Seeds, Inc., Eckenberg Farms, the National Farmers Union of Canada, Genetics International, the International Federation of Organic Agriculture Movements ("IFOAM"), and the International Commission on the Future of Food and Agriculture.

Arkansas Rice Growers Association: ARGA is an association of rice growers. ARGA promotes Arkansas rice to domestic and international trade partners. Arkansas produces almost half of all U.S. rice, more than sixty percent of all long grain rice and an even larger percentage of long grain rice seed. Approximately half of all U.S. grown rice is sold for export. The international rice market has thus far rejected genetically engineered (GE) rice.

ARGA's members experienced severe financial losses after the long grain rice supply was unintentionally genetically contaminated. The genetic contamination of long grain rice cost the U.S. rice industry over one billion dollars in 2006. These losses are clearly significant and far from harmless.

ARGA members did not intend to grow genetically engineered rice, thus their situation is similar to that of the conventional and organic alfalfa growers represented by Respondents who do not intend to

grow GE alfalfa. Despite repeated official assurances that genetic contamination of rice from field trials was highly improbable, ARGA's members have experienced and been harmed by the consequences of transgenic contamination, and have been forced to abandon entirely certain strains of rice that are permanently contaminated – once the genetic contamination is in the DNA of the rice, it cannot be taken out. ARGA believes that it is inequitable for conventional and organic farmers to be forced to bear the economic burdens imposed by those who chose to grow transgenic alfalfa. The story of how genetic contamination has hurt ARGAs' members and the entire U.S. rice industry provides insight into the effects of genetic contamination.

ARGA's hope is that alfalfa farmers are protected from similar contamination so they do not have to suffer the devastating market losses experienced by ARGA members. ARGA intends to assist this Court by showing that the district court's injunction is necessary to prevent the kinds of harm to farmers that not only can, but indeed have already occurred.

Rice Producers of California: RPC is an organization of California rice farmers. California is the second largest rice growing state in the US, and almost 50% of the California rice crop is exported. RPC's mission is to advocate for the economic viability of rice farming in California. RPC has a long history of involvement on marketing issues surrounding the genetic engineering of crop plants, specifically rice. In 2006, RPC commissioned a survey of international buyers of California rice and found that com

mercial production of GE rice, or a contamination event involving GE rice, would have a severe, negative impact on farmers ability to market their crop internationally. Our findings were later shown to be correct by the genetic contamination of Southern US long grain rice.

The New England Farmers Union is a regional chapter of the National Farmers Union working in six New England states. New England Farmers Union represents the interests of small family farmers and promotes the benefits of agriculture for the region. New England farmers, especially dairy and grass fed beef producers, rely on forage plants like hay and alfalfa. The latter is known as "the queen of forages." Because it is perennial, GE alfalfa would certainly cross-pollinate, and would thereby make alfalfa unavailable to organic dairy farmers, and to farmers who rely on conventional alfalfa, having a devastating impact on this fast growing market sector.

Community Alliance with Family Farmers: CAFF is a 30-year-old non-profit membership organization with some 2,000 members nationally, about half of them farmers in California, which works to develop sustainable agriculture and local food systems. CAFF has for more than ten years supported a cautious approach to genetically modified crops, asking that extensive research and testing be conducted to ensure that farmers will not have their conventional crops unintentionally contaminated. Many CAFF members grow conventional alfalfa and CAFF supports a thorough analysis of the potential impacts

of Roundup-read alfalfa prior to its release into the environment.

Fedco Seeds, Inc.: Fedco sells vegetable, flower and herb seeds, seed potatoes and onion sets, fruit trees, ornamentals, berry bushes, perennials, bulbs, soil amendments, cover crops, tools supplies and books for farmers and gardeners. A sizable portion of Fedco's market will not tolerate GE contamination. Fedco has therefore adopted the policy that it will not knowingly sell any transgenic varieties or those contaminated with genetically modified organisms (GMOs). Fedco has suffered losses because of its inability to sell certain sweet corn lots due to the presence of GMOs. Overturning the district court ruling in the alfalfa case poses a potential threat to the purity of other crops by setting a bad precedent in failing to uphold a strict interpretation of NEPA.

Genetics International is a California-based company formed in 1984 to offer distributors diverse germplasm from a range of breeding programs under one single brand. Successfully introduced throughout the Middle East, this innovative, fully integrated model is now being expanded to other world markets. Genetics International exports conventional alfalfa seed to the Middle East, including Saudi Arabia.

Eckenberg Farms is one of world's largest producers of hay cubes. Based in Washington State, Eckenberg Farms supplies premium quality hay cubes, compressed hay bales and a wide range of other premium forage products to customers around the

world. Eckenberg Farms exports alfalfa hay internationally, including to Japan.

International Federation of Organic Agriculture Movements: IFOAM, based in Bonn, Germany, is a grassroots and democratic organization that currently unites 750 member organizations in 116 countries. IFOAM believes in the freedom of choice for both farmers and consumers to choose non-GE varieties, and the protection of farmers' fundamental property rights and economic independence.

International Commission on the Future of Food and Agriculture, based in Italy, aims to ensure that food and agriculture become more socially and ecologically sustainable. The Commission works with regional governments in Europe to develop "GMO [genetically modified organism] free" regions and to instead promote agro-ecological farming methods. GMO alfalfa and herbicide tolerant ("HT") crops are antithetical to the goals of the Commission and as such we wish to avoid the exporting of GMO varieties that could contaminate European crops and food.

SUMMARY OF ARGUMENT

Petitioner Monsanto and Federal Respondent Animal and Plant Health Inspection Service (APHIS) put the alfalfa cart before the horse. They want the court to allow the planting of genetically engineered alfalfa *before* NEPA review is completed. Monsanto and APHIS have it exactly backward. NEPA review must be completed *before* the federal action at issue is taken, not after. NEPA review must precede federal

action so that the agency can determine based on a full administrative record whether to approve the action at all, and whether and what type of mitigation measures are required to prevent unwanted environmental consequences from the *proposed* federal action. Otherwise, agencies could proceed with projects ranging from construction of dams, to forest clear cuts, to nuclear power plants and then conduct NEPA review after the project is already built. This would render NEPA dead letter. The statutory language and Supreme Court case law prevents such an absurd outcome.

This Court has pointed out that NEPA review must occur *before* project approval, not after. In *Andrus v. Sierra Club*, 442 U.S. 347, 351 (1979), this Court emphasized that the NEPA regulations promulgated by the Council for Environmental Quality (CEQ) state:

> An agency shall commence preparation of an environmental impact statement *as close as possible to the time the agency is developing or is presented with a proposal* . . . so that preparation can be completed in time for *the final statement to be included in any recommendation or report on the proposal.* The statement shall be prepared early enough so that it can serve practically as an important contribution to the decisionmaking process and *will not be used to rationalize or justify decisions already made.* . . . For instance:

> (a) For projects directly undertaken by Federal agencies *the environmental impact statement shall be prepared at the feasibility analysis (go-no go) stage* and may be supplemented at a later stage if necessary. . . ."

Andrus v. Sierra Club, 442 U.S. 347, 351 (1979), quoting, 43 Fed. Reg. 55995 (1978) (codified at 40 CFR § 1502.5) (emphasis added).

Similarly in *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 109 S. Ct. 1851, 104 L. Ed. 2d 377 (1989), this Court stated that NEPA "promotes its sweeping commitment" to environmental integrity "by focusing Government and public attention on the environmental effects of *proposed agency action*." (Id. at 371) "By so focusing agency attention, *NEPA ensures that the agency will not act on incomplete information, only to regret its decision after it is too late to correct*." (Id.)

This Court's jurisprudence is clear. NEPA review must occur at time of "proposed agency action," at the "go-no-go" stage, and not after project approval when the agency may act on "incomplete information, only to regret its decision after it is too late to correct," or when the NEPA document may do nothing more than "rationalize or justify decisions already made."

Nevertheless, APHIS and Monsanto seek to proceed with their approval of genetically engineered alfalfa, before completing NEPA review, with only minimal safeguards. While Monsanto's brief is re

plete with expert "evidence" suggesting that the safeguards proposed by APHIS will be adequate, this is precisely the type of analysis that must occur in the Environmental Impact Statement (EIS), subject to public review and comment, not in a legal brief prepared by lawyers and reviewed by judges with no expertise in the field. The trial court and Ninth Circuit plainly followed this Court's directives in this respect.

The trial court pointed out that it is not an expert "super agency," and that the court should let the agency do its job after the completion of the final EIS and review of all public and expert comments submitted. The trial court stated:

> So I'm not an environmental agency... I could be like a super environmental agency engaged in balancing all these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And number two, it isn't my job .... I should stop things in its place until the Government has discharged its duty given to it by the right of Congress of the United States.

Pet.App.417a.

The trial court did not ban genetically engineered alfalfa. Rather, it merely held that NEPA review should be conducted first, before this crop that exists nowhere in nature is unleashed upon the world, in order to analyze what environmental impacts may occur, and what measures are necessary to protect against those impacts. The whole point of

NEPA is to conduct the review *before* there is an impact on the environment.

Indeed, there is no dispute that genetically engineered alfalfa poses environmental risks. No party has challenged Judge Breyer's well-reasoned ruling that an environmental impact statement (EIS) is required under NEPA. Further, all parties agree that some form of injunctive relief is required. Monsanto and APHIS merely argue that the scope of injunctive relief ordered by the trial court was too broad and should have been more narrowly tailored. All of the parties agree that there is a risk of cross-pollination between genetically engineered alfalfa and conventional alfalfa. The only question is what steps are necessary to protect against that threat. This is precisely the type of situation where NEPA review is required *ante hoc*, not *post hoc*. Only after the EIS is complete will APHIS be able to determine, based on a full record, what mitigation measures are required to adequately safeguard the environment against the threat of genetic contamination that all parties agree exists.

ARGUMENT

I. LEGAL STANDARD

A. The Trial Court Complied with NEPA by Applying the Four-Part Injunction Standard and Enjoining the Proposed Federal Action Pending Completion of NEPA Review

All parties agree that a plaintiff seeking a preliminary injunction must establish: (1) a likelihood of success on the merits; (2) a likelihood of irreparable harm in the absence of injunctive relief; (3) that the balance of equities tips in favor of the party seeking injunctive relief; and (4) that an injunction is in the public interest. *Winter v. Natural Resources Defense Council*, 129 S. Ct. 365, 374 (2008). As discussed in Respondents' brief, the District Court and Ninth Circuit, (Pet.App.11a, 13a), applied all four factors in issuing the injunction in this action.

Indeed, Petitioners acknowledge that an injunction is appropriate in this action. They merely challenge the scope of the injunction issued by the District Court, contending that it is overly broad. Since Petitioners contend that an injunction may only be issued based on the four factors set forth in *Winter*, and Petitioners admit that injunctive relief is appropriate in this action, by necessary implication, Petitioners must admit that all four prongs of the injunction standard have been satisfied. Thus, this case is nothing like *Winter*, where the lower courts applied the wrong legal standard. Here, the district court and Ninth Circuit applied the proper legal standard, and there is no dispute that injunctive relief is appropriate.

The only dispute is as to the scope of the injunction. Here, Petitioners bear a much heavier burden. Flexibility is a hallmark of equity jurisdiction. "The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it."

Weinberger v. Romero-Barcelo, 456 U.S. 305, 312, (1982), quoting *Hecht Co. v. Bowles*, 321 U.S. 321 (1944). A district court has "considerable discretion in fashioning suitable relief and defining the terms of an injunction" and appellate review of those terms is "correspondingly narrow." *Lamb-Weston, Inc. v. McCain Foods, Ltd.*, 941 F.2d 970, 974 (9th Cir. 1991). "Absent the clearest command to the contrary from Congress, federal courts retain their equitable power to issue injunctions in suits over which they have jurisdiction." *Califano v. Yamasaki*, 442 U.S. 682, 705 (1979). As discussed above, the district court's injunction and the findings on all four prongs of the injunction standard are supported by the record and are not clearly erroneous.

B. NEPA Contains a Strong Statutory Preference that Environmental Review Should Generally Precede Federal Action.

This Court has made clear that NEPA's statutory language generally requires NEPA review to be completed ***prior*** to the commencement of the federal action at issue. In *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989), this Court stated, "NEPA ensures that important effects will not be overlooked or underestimated only to be discovered after resources have been committed or the *die otherwise cast*." (Emphasis added); see also, *Andrus*, 442 U.S. at 351-352, n. 3, 99, quoting 40 CFR § 1502.5 (1979). A statute may restrict the court's equity jurisdiction. *Weinberger v. Romero-Barcelo*, 456

U.S. 305, 313 (1982); *TVA v. Hill*, 437 U.S. 153, 173 (1978).

This Court has explained that NEPA review must occur *prior* to project approval. In *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 371 (1989), this Court stated, "[b]y so focusing agency attention, NEPA ensures that the agency will not act on incomplete information, *only to regret its decision after it is too late to correct.*" (emphasis added); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989); *Andrus v. Sierra Club*, 442 U.S. 347, 351 (1979). Placing NEPA review prior to agency action ensures that the agency considers the potential consequences of its proposed action as well as potential mitigation measures and alternatives to the proposed course of action. See *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 351-352, (citing 40 CFR §§ 1508.25(b), 1502.14(f), 1502.16(h), 1505.2(c) (1987)); *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 558 (1978). An EIS must be prepared "early enough so that it can serve practically as an important contribution to the decisionmaking process and *will not be used to rationalize or justify decisions already made.*" *Andrus*, 442 U.S. at 351-352, n. 3, 99 (quoting 40 CFR § 1502.5 (1979) (emphasis added).

The Court in *Winter* recognized that application of NEPA's general preference for environmental review prior to federal action was not possible in that case because the action at issue was not a "new type of activity," but instead had been ongoing for 40

years, and extensive environmental review had already occurred. (*Winter v. NRDC*, 129 S. Ct. at 376).

By contrast, in this case, APHIS does propose a "new type of activity" -- namely the first ever unregulated, open-pollinated, perennial, genetically engineered crop proposed to be unleashed upon the environment. Under the standards articulated in *Winter*, until NEPA review is completed, APHIS cannot determine whether to approve the project at all, or whether and what type of mitigation measures to impose to safeguard the environment.

Thus, the district court's order in this case, enjoining federal action pending completion of NEPA review is completely consistent with the language and purpose of NEPA, and this Court's NEPA jurisprudence. The district court properly applied all four prongs of the injunction standard and complied with NEPA's directive requiring environmental review prior to federal action.

II. THE DISTRICT COURT MADE ALL NECESSARY FINDINGS TO SUPPORT ITS INJUNCTION PROTECTING FARMERS FROM IRREPARABLE HARM FROM TRANSGENIC CONTAMINATION PENDING COMPLETION OF NEPA REVIEW.

A. Success on the Merits.

Respondents demonstrated actual success on the merits – much more than a likelihood of success.

An EIS is required for the proposed APHIS action. Petitioners do not even challenge the district court's ruling on the merits.

B. Without the Injunction, Farmers Will Be Irreparably Harmed.

1. The District Court Properly Held that the Injunction was Necessary to Prevent the Irreparable Harm of Transgenic Contamination

The district court cited evidence that despite the imposition of safeguards almost identical to those proposed by APHIS, extensive transgenic contamination had already occurred in alfalfa crops in at least four separate states, causing irreparable harm. Contractual conditions required separation distances between transgenic and conventional alfalfa ranging from 900 feet to three miles (depending on the type of bees used for pollination), JA 263, 280-81, 615, required growers of transgenic alfalfa hay to harvest their crop at or before 10 percent bloom, JA 260-61, 334, 624, and required growers of both seeds and hay to thoroughly clean tractors, combines, and other equipment used to harvest and process transgenic alfalfa. JA 329; see also JA 271, 283-84, 287-88, 325, 349.

Despite these safeguards, conventional alfalfa seed producers experienced contamination by transgenic alfalfa in at least four different states – Montana, Wyoming, California and Idaho. JA 1008-10,

1013-14, 1017-19, 1022-24, 670-75; see also JA 630, 663-64, 666. Transgenic contamination was detected at up to 1.5 miles from the RRA source, despite predictions that the bees involved would carry the engineered gene no more than 900 feet. JA 1018.

Based on this and other evidence, the district court properly held that the proposed APHIS conditions were not adequate to prevent transgenic contamination, and the more comprehensive injunction was required pending the completion of NEPA review.

2. Transgenic Contamination Has Plagued Rice Farmers Under Similar Circumstances.

A recent report of the United States Government Accountability Office ("GAO") concluded that "Unauthorized releases of GE crops into food, animal feed, or the environment beyond farm fields have occurred, and *it is likely that such incidents will occur again*" (emphasis added).[2] The report points to at least six incidents of GE crops contaminating conventional crops, with the most prominent involving GE varieties of corn and rice. This brief focuses primarily on the experiences of *Amici* Arkansas Rice Growers.

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[2] GAO, Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring (November 2008) GAO-09-60, p. 1.

On August 18, 2006, the United States Secretary of Agriculture, Mike Johanns, announced that transgenic material had contaminated the U.S. long grain rice supply.[3] That very day the price of long grain rice futures contracts traded on the Chicago Board of Trade began to decline.[4] Two days later, Japan banned all U.S. long grain rice imports.[5] Five days later, the European Union, which previously imported 5-6% of all U.S. long grain rice, announced it would no longer accept long grain rice from the U.S. unless it was tested and certified free of GE grains.[6] Just eleven days after the contamination was announced, the value of the U.S. long grain rice crop had fallen by $135 million.[7] Analysts realized that, despite a promising forecast and the hard work already invested, farmers would not even come close

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[3] Press Release, United States Department of Agriculture, Release No. 0306.06: Investigation of Regulated Rice in Commercial Rice Samples (Aug. 18, 2006), http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2006/08/0306.xml.

[4] U.S. Rice Producers Association, Analysis of GM Impact of Rice on Rice Industry (Feb. 19, 2008) (unpublished spreadsheet, on file with U.S. Rice Producers Association).

[5] *Japan Bans 'Contaminated' US Rice*, BBC News, Aug 21, 2006, available at http://news.bbc.co.uk/2/hi/science/nature/5271384.stm.

[6] Press Release, Europa, *Commission requires certification of US rice exports to stop unauthorised GMO entering the EU*, Aug 23, 2006, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/1120.

[7] Press Release, Arkansas Rice Growers Association, Rice Producer Update (Aug 29, 2006), http://www.arkansasricegrowers.com/gm.asp.

to breaking even in 2006.[8] The producers of an international food staple suddenly had to worry about feeding their own families.

In the months after this initial contamination was discovered, testing revealed two more contamination events involving transgenic rice strains.[9] APHIS, fully aware of the dramatic consequences of growing genetically contaminated rice, issued emergency action notifications to stop the planting of the popular, and now contaminated, Clearfield 131 rice variety.[10] The financial burden imposed by these actions was borne by individual farmers.

a. Contamination Occurred Despite the Imposition of Safeguards

Following the contamination incidents, the United States Department of Agriculture launched a major investigation. On October 5, 2007 USDA an

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[8] Christina Verderosa, *County Farmers Irritated About Genetic Rice Flap*, DeWitt Era-Enterprise, Aug. 30, 2006, http://www.dewittee.com/articles/2006/08/30/news/news01.txt .

[9] Marc Gunther, *Attack of the Mutant Rice*, Fortune Magazine, July 2, 2007, http://money.cnn.com/magazines/fortune/fortune_archive/2007/07/09/100122123/index.htm.

[10] Press Release, USDA Animal and Plant Health Inspection Service, Statement by Dr. Ron DeHaven Regarding APHIS Hold on Clearfield CL131 Long-Grain Rice Seed (Mar. 5, 2007) (on file with author).

nounced the conclusion of its investigation.[11] Despite extensive analysis, USDA concluded that the exact mechanism of the genetic contamination could not be determined.[12]

The transgenic rice responsible for the contamination incident probably entered the rice supply from field trials conducted by an experienced rice breeder at Louisiana State University, despite aggressive measures to prevent such contamination, including buffer zones four times larger than recommended by the manufacturer.[13]

In its report, USDA admits that even with proper procedures, it may be impossible to prevent the low-level presence (LLP) of transgenic plant material in conventional seeds and grains. It states, "[t]hese occurrences can result from natural processes such as the movement of seeds or pollen or human-

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[11] Press Release, United States Department of Agriculture, USDA Concludes Genetically Engineered Rice Investigation (Oct. 5, 2007), http://www.usda.gov/wps/portal/usdahome?contentidonly=true&contentid=2007/10/0284.xml; USDA, Report of Liberty Link Rice Incidents 1 (2007), www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

[12] USDA, Report of Liberty Link Rice Incidents 1 (2007), www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

[13] Marc Gunther, *Attack of the Mutant Rice*, Fortune Magazine, July 2, 2007, http://money.cnn.com/magazines/fortune/fortune_archive/2007/07/09/100122123/index.htm.

mediated processes associated with field testing, plant breeding, or seed production."[14] USDA's Biotechnology Regulatory Services "continually examines confinement measures, including isolation distances, to insure that they are adequate; however, *these measures still might not prevent 100 percent of LLP occurrences*."[15] (emphasis added).

Agriculture consultant, Dr. E. Neil Blue, concludes that buffer zones proposed by APHIS will be inadequate to prevent transgenic contamination of conventional alfalfa. Dr. Blue points out that similar safeguards did not protect the canola crop. He states, "The extent of the penetration of contaminated seed into the canola seed supply is now so deep that segregating GE from non-GE seed will not help at this point (http://www.grain.org/front/)."[16]

In light of USDA's conclusions following the transgenic rice contamination incident, it defies logic for APHIS to claim that its proposed measures for the planting of Roundup Ready alfalfa can prevent transgenic contamination of conventional alfalfa. ARGA's experience demonstrates that even very low levels of

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[14] USDA, Report of Liberty Link Rice Incidents 2 (2007), www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf.

[15] *Id.*

[16] Comments of Dr. E. Neil Blue, A Review of the Draft Environmental Impact Statement, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status (March 2010), APHIS-2007-0044-10172.1.

transgenic material in a crop can cause devastating and extensive losses for farmers. Contamination of long grain rice led to severe market losses despite the fact that the genetic material was found at a rate of 0.06 percent or six out of 10,000 rice kernels.[17]

b. Rice Farmers Suffer Ongoing Harm Resulting from Transgenic Contamination

APHIS's December 4, 2006, deregulation of GE rice allowed long grain rice to be sold in the U.S., albeit at discounted prices.[18] However, deregulation did not affect the stance of international trade partners. Many formerly enthusiastic trade partners, including the European Union, Japan, Russia, Iraq, Canada, and Mexico, continue to either impose stringent testing requirements on U.S. long grain rice or reject it outright.[19] Farmers must bear the financial burdens imposed by these new testing requirements and market losses.

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[17] Christina Verderosa, *County Farmers Irritated About Genetic Rice Flap*, DeWitt Era-Enterprise, Aug. 30, 2006, http://www.dewitt-ee.com/articles/2006/08/30/news/news01.txt.

[18] Bayer CropScience; Extension of Determination of Nonregulated Status to Rice Genetically Engineered for Glufosinate Herbicide Tolerance, 71 Fed. Reg. 70,360, 70362 (Dec. 4, 2006) (to be codified at 7 CFR pt. 340).

[19] USARice.com, *U.S. Rice Export Markets Impacted by the Presence of LLRICE601*, http://www.usarice.com/industry/communication/exportimpact.pdf (last visited Feb. 24, 2008).

Lost markets and new testing requirements are not the only ongoing harms. To contain the contamination, farmers no longer plant the contaminated varieties, Cheniere and Clearfield 131. For many farmers, these were the varieties of choice. The abandonment of these varieties has led to seed shortages, as farmers seek out less popular, uncontaminated seed varieties. Farmers are therefore forced to grow less desirable rice varieties. In addition, farmers are still overcoming the cost of having had to decontaminate their fields, machinery, storage facilities, and transportation systems.[20] Some rice farmers have gone out of business or have gotten out of the business, deciding the business of growing rice is too risky.

While economic loss alone is generally not irreparable, when the loss is so severe that is amounts to the "loss of one's business," the harm is irreparable. *American Trucking Ass'n v. City of Los Angeles*, 559 F.3d 1046, 1059 (9th Cir. 2009).

c. Without the Injunction on New Planting of RRA, Alfalfa Famers are Likely to Suffer the same type of Irreparable Harms Endured by Rice Farmers.

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[20] Press Release, Arkansas Rice Growers Association, Rice Farmer Liabilities Focus of ARGA on GMO Debate (Jan. 3, 2007), http://www.arkansasricegrowers.com/gm.asp.

While there are certainly differences between rice and alfalfa, one significant similarity is that APHIS has provided assurance to farmers of both crops that transgenic contamination of their crops from nearby GE plots is nearly impossible. Nonetheless, the U.S. long grain rice supply was contaminated, even though the transgenic rice was grown only by experts in tightly-controlled field trials.[21] Another similarity lies in the type of GE trait; both RRA and the contaminated rice strains contain a trait for herbicide tolerance.[22]

Petitioners contend that Roundup Ready alfalfa can be grown on a million acres with no real threat of contamination because farmers will promise to follow the measures proposed by APHIS. However, in view of the above-described actual experiences, these assurances that there will be no contamination of organic and conventional alfalfa are speculative and lack credibility. Long grain rice is a self-

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[21] GE rice was a regulated article when the contamination was announced, but was deregulated several months later. Bayer CropScience; Extension of Determination of Nonregulated Status to Rice Genetically Engineered for Glufosinate Herbicide Tolerance, 71 Fed Reg. 70,360, 70362 (Dec. 4, 2006) (to be codified at 7 CFR pt. 340). In contrast, GE alfalfa was deregulated in 2005, but was reregulated as a result of inadequate environmental analysis. Return to Regulated Status of Alfalfa Genetically Engineered for Tolerance to the Herbicide Gylphosate, 72 Fed. Reg. 13,735, 13,736 (Mar. 23, 2007) (to be codified at 7 CFR pt. 340).

[22] The contaminated rice strains contained the GE trait which confers tolerance to the herbicide LibertyLink, or glufosinate. RRA is genetically engineered for tolerance to Roundup, or glyphosate.

pollinated annual plant that was only grown in field trials, yet it contaminated large portions of the long grain rice crop. Alfalfa is an open-pollinated plant, which is even more susceptible to cross-pollination. Yet, Petitioners would like to see it grown on hundreds of thousands of acres, *before* NEPA review is completed. Thus, contamination of organic and conventional alfalfa by Roundup Ready alfalfa is even more likely.

Alfalfa farmers, like rice farmers, rely on the purity of their product to ensure its marketability. Importing businesses in several countries including Japan, which imports 75% of the alfalfa exported from the U.S., have stated that their markets do not want RRA and will reject alfalfa contaminated by RRA. Pet.App. 30a, 40a; JA 120, 154, 243, 354, 409-11, 420-23, 433, 451, 1070-71. Genetic contamination of conventional and organic alfalfa would likely lead to adverse consequences for alfalfa growers similar to those suffered by long grain rice farmers.

The proposed deregulation of genetically engineered alfalfa is likely to have a significant impact on export markets, especially Saudi Arabia, Japan, and South Korea. According to the draft environmental impact statement already prepared by APHIS, these three countries "all have approval processes for GE products and labeling requirements." For alfalfa hay, Japan and the Republic of Korea are the main players. "Approximately three-fourths of U.S. alfalfa hay exports go to Japan each year" while approximately

13 to 16 percent goes to the Republic of Korea.[23] Exports to Japan and Korea exceed $159 million dollars annually.[24]

APHIS's own EIS describes Japan's attitude as "zero tolerance" when it comes to non-approved GE foods, and they have a rigorous inspection process, testing "up to 50% of all cargoes." "Labeling is mandatory for all GE foods as long as GE material can be detected, the GE ingredient is one of the first three ingredients of a product, and the GE material accounts for more than five percent of the total weight."[25]

One American exporter expressed concern in the EIS that "Japan's reaction to Monsanto's sale of GE alfalfa seed in Washington State could be extreme, including chances of a boycott or other negative reaction" and that "the consequences of such a reaction will fall primarily on the shoulders of the Washington State hay industry and on the state's economy, not Monsanto, and Monsanto either does not appreciate, or is not concerned about, the heightened level of Japanese consumer awareness of, and

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23 http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf, p. 54

24 *Id.* Table R-3, Appendix R, p.R-6; see also, Comments of Dr. E. Neil Blue, A Review of the Draft Environmental Impact Statement, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status (March 2010), APHIS-2007-0044-10172.1.

25 *Id.* p. 141

phobia for, GE products, particularly with regard to milk and dairy products and the perceived danger to their children's diets."[26]

"Korea has similar approval processes and labeling requirements as Japan" and does not require labeling of processed foods with "non-detectable levels of GE material such as dairy, meat, and vegetable oils."[27] "As in the case of Japan, there is evidence of consumer negative views of GE products" which could result in a significant economic impact, especially as demand for labeling expansion increases.[28] Keeping these important markets for US alfalfa producers may prove difficult if the GE alfalfa becomes unregulated.

According to USDA's December 2009 draft EIS on the deregulation of GE alfalfa, [29] for alfalfa seed, the most important export market is Saudi Arabia.[30] Saudi Arabia is the largest customer for U.S. alfalfa seed, followed by Mexico, Argentina, and Canada.[31]

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[26] *Id.* Appendix B-40

[27] *Id.* Appendix R-10

[28] *Id.* Appendix R-12

[29] http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf

[30] APHIS. (2009). Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement. 142.

[31] http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf, Table R-1.

Saudi Arabia has said that it will not purchase GE alfalfa seeds, and whether they would "continue purchasing non-GE alfalfa seeds from the United States would likely depend on the extent to which non-GE alfalfa seed producers are able to avoid unintended presence of GE alfalfa traits."[32] For US alfalfa seed producers, this could spell losses of more than $38 million annually.[33]

APHIS admits in the EIS that "deregulation of GT [glyphosate-tolerant] alfalfa could imply losses in exports of alfalfa seed and hay to the main U.S. clients" and that "[a]ny losses are unlikely to be regained in the future, since the trust established by lasting commercial relationships is often valued in international trade."[34] If GE alfalfa is deregulated, the burden of sustaining an export market for alfalfa seed to Saudi Arabia will fall on the shoulders of seed producers, who may find it increasingly difficult to maintain purity.

Lifting the district court's injunction is likely to result in the same type of ruinous economic loss to alfalfa farmers as befell rice farmers. As with rice

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[32] APHIS. (2009). Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement. 142-143.

[33] APHIS. (2009). Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement. Appendix R-6.

[4] APHIS. (2009). Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement. 178.

farmers, when the loss is so severe that is amounts to the "loss of one's business," the harm is irreparable. *American Trucking Ass'n v. City of Los Angeles*, 559 F.3d at 1059.

3. Without the Injunction Farmers Will Be Irreparably Harmed by their Loss of Choice to Grow Conventional Alfalfa.

Judge Breyer's merits decision found that a farmers' loss of his right to farm the crop of his choice because of unwanted transgenic contamination from GE crops was a cognizable harm that required an EIS:

> "A federal action that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, is an undesirable consequence: another NEPA goal is to "maintain, wherever possible, an environment which supports diversity and variety of individual choice." 42 U.S.C. § 4331(b)(4) ... An action which potentially eliminates or least greatly reduces the availability of a particular plant--here, non-engineered alfalfa--has a significant effect on the human environment."

This decision was *not* appealed and cannot be challenged here.

As discussed above, one of the most troubling aspects of the transgenic rice contamination incidents was that farmers who had no intention of growing transgenic rice were unwittingly forced to grow transgenic rice due to cross-pollination or other routes of contamination. These farmers lost their freedom to choose whether to grow transgenic rice, but suffered all of the adverse market consequences of growing the genetically engineered varieties.

Farmer also lost their freedom to choose entire varieties of rice that become contaminated with transgenics. To contain the contamination, farmers no longer plant the contaminated varieties, Cheniere and Clearfield 131, which were previously very popular rice varieties. These farmers have lost their ability to plant the rice varieties of their choosing due to unwanted and unintentional transgenic contamination.

Similar contamination of alfalfa has occurred in at least four states. The injunction is necessary to prevent irreparable harm caused by biological contamination and the resulting loss of farmers' right to choose to grow non-GE crops.

4. The District Court Injunction is Necessary to Prevent Irreparable Harm Caused by Roundup-Resistant Weeds.

The district court held that APHIS failed to assess the environmental significance of the anticipated proliferation of glyphosate-tolerant weeds (Roundup-

Resistant Weeds) – a side-effect of deregulation that APHIS did not dispute. Pet.App.45a-47a. Adoption of RRA would necessarily result in an increase in herbicide use, since that is the very purpose or Roundup Ready crops (including corn, rice, and soybeans). JA 114-43; see also JA 239-44. This, in turn, would result in a proliferation of glyphosate tolerant weeds, thereby driving farmers into a cycle of applying *even more* glyphosate or to employ other herbicides. JA 114-26, 131-43; see JA 239-44, 678-83, 707-19.

Alfalfa is a vigorous perennial crop that outcompetes weeds and thus is grown mostly without herbicides.[35] Roundup Ready alfalfa would encourage many farmers who presently use little or no glyphosate (active ingredient of Roundup) to use it, up to four times per year. USDA estimated that the "potential amount of glyphosate due to adoption of GT [glyphosate-tolerant] alfalfa" was 142,761,960 lbs. per year.[36] This is a huge amount of glyphosate, roughly the quantity now used in all of American agriculture.[37]

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[35] USDA (1999). "Agricultural Chemical Usage: 1998 Field Crops Summary," USDA's National Agricultural Statistics Service, May 1999, p. 9. Just 7% of alfalfa hay acres were treated with herbicides.

[36] USDA (2009). "Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status. Draft Environmental Impact Statement," Nov. 2009, Appendix N at N17-N18.

[37] See EPA (2009). "Glyphosate Summary Document Registration Review: Initial Docket," Environmental Protection Agency, June 2009, p. 12, for figure of 135 million lbs. acid equivalents of glyphosate.

Roundup Ready crops are genetically engineered to be resistant to glyphosate and therefore, farmers can put as much glyphosate as they want on the crops. Genetically-modified (GM) soybeans, corn and cotton have increased overall herbicide use in the U.S. by 383 million lbs. over the first 13 years of their cultivation, from 1996 to 2008, versus what would have been applied in their absence. Roundup Ready crops are engineered to survive direct application of glyphosate (active ingredient of Roundup) to kill nearby weeds. The ability to spray Roundup Ready crops repeatedly with glyphosate throughout the growing season makes weed control easier and less labor intensive. After a few years, however, the exclusive use of glyphosate that is common with Roundup Ready crops drives the evolution of glyphosate-resistant weed populations – just as overused antibiotics foster resistant bacteria.

Farmers initially respond to resistant weeds by spraying more glyphosate, which in turn drives higher levels of resistance. This is the major factor responsible for the enormous increase in the intensity of glyphosate use in the Roundup Ready crop era, as revealed by USDA pesticide usage data. The annual amount of glyphosate applied per acre has doubled for soybeans (1996 to 2006) and tripled on cotton (1996 to 2007), clear signs that weeds are becoming resistant. In just one decade, glyphosate-resistant weeds have expanded from 1 species on a few thousand acres in California to 10 species on as much as

11.4 million acres in 22 states,[38] with the majority of resistant weed populations expanding.

Leading weed scientist Dr. Stephen Powles recently warned that glyphosate-resistant weeds pose "a looming threat to global cropping and food production."[39] Dr. Alan York at North Carolina State University regards glyphosate-resistant weeds in cotton as "potentially the worst threat since the boll weevil."[40] According to Dr. Micheal Owen of Iowa State University: "Right now, we are on the edge of a precipice that we could step off [of] in the next two years."[41]

Weeds cost U.S. agriculture a substantial $33 billion per year in lost productivity, despite $7 billion

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[38] Center for Food Safety's compilation of data from glyphosate-resistant weed reports listed by the Weed Science Society of America at http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go/. Glyphosate is the only member of the "Glycines" herbicide class. Acres infested reported in ranges, 11.4 million is the aggregate, upper-bound estimate.

[39] Powles, S.B. (2010). "Gene amplification delivers glyphosate-resistant weed evolution," Commentary, *Proceedings of the National Academy of Sciences* 107: 955-956.

[40] Minor, E. (2006). "Herbicide-resistant weed worries farmers," Associated Press, 12/18/06.

[41] Gullickson, G. (2010). "Reeling from resistance. Weed resistance to glyphosate and other modes of action increase," *Successful Farming*, Jan. 26, 2010.

spent on weed-killers.[42] Resistance to glyphosate is rapidly increasing these losses and costs. Soybeans grown by Mississippi farmer Kenneth Hood were so badly infested with Roundup-resistant pigweed that he had to plow them under, unharvested, while at least 10,000 acres of cotton fields in Georgia have been abandoned as uncultivable.[43] Crittenden County, Arkansas Extension agent Mike Hamilton estimates that an uncontrolled outbreak of glyphosate-resistant horseweed would reduce yields of cotton and soybeans by 50% and 25%, respectively, costing his state's farmers $500 million.[44]

Farmers also resort to increased use of other toxic herbicides. Use of carcinogenic 2,4-D in soybeans increased by 112% from 2005 to 2006;[45] 2,4-D was part of the Vietnam War's Agent Orange. The EPA recently exempted cotton from its ban on use of arsenic-based herbicides specifically to give cotton farmers a badly needed, but toxic, tool to battle resistant pigweed.[46]

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[42] USDA (undated). U.S. Dept. of Agriculture, Agricultural Research Service, Invasive Weed Management Unit, http://arsweeds.cropsci.illinois.edu/.

[43] Robinson, E. (2010). "Old technology coming out the closet," *Delta Farm Press*, 1/12/10; Robinson, E. (2008). "Designing the perfect weed - Palmer amaranth," *Delta Farm Press*, 12/24/08.

[44] James, L. (2005). "Resistant weeds could be costly," *Delta Farm Press*, 7/21/05.

[45] *Ibid.* p. 59.

[46] EPA Arsenic (2009). "Amendment to Organic Arsenicals RED," Letter from EPA's Richard P. Keigwin, Director, Spe-

Losing an herbicide as valuable as glyphosate to resistance hurts all growers, especially non-Roundup Ready growers, many of whom make more appropriate, sparing use of this herbicide. For instance, wheat farmers who use glyphosate moderately because there is no Roundup Ready version available could easily be robbed of glyphosate if resistant weeds spread to their fields from Roundup Ready fields. This would constitute a tragedy of the commons, with weed susceptibility to glyphosate the common resource being squandered.

The latest resistant weed – kochia – illustrates the dilemma.[47] Resistant kochia evolved in corn, soybeans, and cotton,[48] but has the ability to spread to alfalfa, sugar beets and wheat, where it is one of the more problematic weeds,[49] and is already plagued by massive resistance to three other herbicide classes.[50]

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cial Review and Reregistration Division, to Registrant, April 22, 2009.

[47] Gillam, C. (2010). "More US weeds found resisting Monsanto Roundup," *Reuters*, 2/26/10.

[48] http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go. See two entries for "kochia." Though first discovered in 2007, resistance not confirmed until 2010.

[49] Menalled, F.D. & R.G. Smith (2007). "Competitiveness of herbicide-resistant and herbicide-susceptible kochia (*Kochia scoparia* [L.] Schrad.) under contrasting management practices," *Weed Biology and Management* 7: 115-119.

[50] http://www.weedscience.org/Summary/USpeciesCountry.asp?lstWeedID=101&FmCommonName=Go.

Monsanto now blames farmers for resistant weeds. In fact, the company has greatly contributed to the problem by continually advising farmers that exclusive reliance on Roundup Ready crops and Roundup, year-in, year-out, would not lead to weed resistance.[51] A respected Iowa State University agronomist singled out Monsanto's advertisements as precisely the wrong advice to give farmers. Continual use of glyphosate and no other weed control method is the perfect recipe for resistance. "Monsanto's self-serving advice has accelerated the emergence of glyphosate resistance in weeds." *Id.*

The district court's injunction is necessary to protect farmers from the irreparable harm that is likely to be caused by Roundup-Resistant weeds. A final EIS is necessary to analyze this impact and to propose mitigation measures to reduce or eliminate the impact.

C. The Balance of Equities Tips in Favor of the Injunction.

The district court found that "[t]he harm to these farmers and consumers who do not want to purchase genetically engineered alfalfa or animals fed with such alfalfa outweighs the economic harm to Monsanto, Forage Genetics and those farmers who desire to switch to Roundup Ready alfalfa." Pet.App.71a. It found that any lost revenue to peti

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[51] B. Hartzler, Two for the price of one, Iowa State University, (Dec. 17, 2004). http://www.weeds.iastate.edu/mgmt/2004/twoforone.shtml.

tioners did "not outweigh the potential irreparable damage to the environment." *Id.*

As discussed above, if the US alfalfa crop becomes transgenically contaminated, the loss of overseas markets will be permanent. USDA concludes that, "deregulation of GT alfalfa could imply losses in exports of alfalfa seed and hay to the main U.S. clients" and, "[a]ny losses are unlikely to be regained in the future, since the trust established by lasting commercial relationships is often valued in international trade."[52]

By contrast, the delay for Petitioners is only temporary, until the EIS is completed to determine safeguards necessary to protect the US food supply. Petitioners are seeking to plant an illegal and new product that could harm others. *Amici* simply want to plant as they always have and provide no danger to anyone. The balance of harms goes only one way in this case.

Judge Breyer was correct in finding that the environmental harm that would be caused by transgenic alfalfa far outweighed the purely economic harm that Monsanto and Forage Genetics may suffer. This holding was entirely consistent with this Court's instruction that:

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[50] APHIS. (2009). Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement. p. 178.

> Environmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, i.e., irreparable. If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment.

Amoco Production Co. v. Village of Gambell, 480 U.S. 531, 545 (1987).

D. The Injunction is in the Public Interest.

The district court found that petitioners' proposed "expansion of the [RRA] market pending the preparation of the EIS" was "unprecedented" and was not in the public interest. Pet.App.72a-75a. Judge Breyer's ruling on this point was completely consistent with the public interest embodied by the legislature in NEPA and articulated by this Court on numerous occasions that NEPA review should generally precede the proposed federal action.

As discussed above, the EIS should be prepared "*as close as possible to the time the agency is developing or is presented with a proposal* . . . so that it can serve practically as an important contribution to the decisionmaking process and *will not be used to rationalize or justify decisions already made.*" *Andrus v. Sierra Club*, 442 U.S. 347, 351 (1979). "*NEPA ensures that the agency will not act on incomplete in*

formation, only to regret its decision after it is too late to correct." Marsh v. Oregon Natural Resources Council, 490 U.S. 360, (1989).

Furthermore, this Court has long recognized that "ensur[ing] the purity of the Nation's food supply," is one of the most important functions of government in protecting the public interest. *Young v. Community Nutrition Institute*, 476 U.S. 974, 976 (1986); *Sligh v. Kirkwood*, 237 U.S. 52 (1915).

The district court's injunction is the only means to protect the core values set forth by the legislature in NEPA. The legislature's intent, set forth in law, is the clearest articulation of the public interest. As this Court stated in another NEPA case, "[t]he very existence of the statutes indicates that protection of parkland was to be given paramount importance." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413 (1971). The district court's injunction vindicates the public interest enshrined by Congress in NEPA, and protects one of the Nation's most critical assets – its food supply.

CONCLUSION

For the foregoing reasons, *Amici Curiae* respectfully request that this Honorable Court *affirm* the judgment of the Court of Appeals.

DATED: April 2, 2010

Respectfully submitted.

_____/s/_____

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AMICUS CURIAE BRIEF

No. 09-475

IN THE

Supreme Court of the United States

MONSANTO COMPANY, ET AL.,
Petitioners,
v.
GEERTSON SEED FARMS, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICI CURIAE* DINAH BEAR, ROBERT GLICKSMAN, OLIVER HOUCK, DANIEL MANDELKER, THOMAS McGARITY, ROBERT PERCIVAL, ZYGMUNT PLATER, NICHOLAS ROBINSON, AND GARY WIDMAN IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici seek to ensure equity remains a viable enforcement tool for courts to fulfill the statutory purposes embodied in the National Environmental Policy Act (NEPA) and other environmental laws. If Petitioners' view prevails, *amici* fear courts will foreclose injunctive relief unless environmental harms are proven more likely than not to occur, an unmerited departure from equity's traditional role. For these reasons, two former General Counsels to the Council on Environmental Quality (CEQ) and seven law professors submit this *amicus curiae* brief in support of Respondents Geertson Seed Farms, et al.

Amici Dinah Bear and Gary Widman are former General Counsels to CEQ in the Executive Office of the President whose service extends throughout much of the lifetime of NEPA.[2] Their combined experience interpreting and implementing NEPA spans five presidential administrations. Ms. Bear and Mr. Widman remain strongly committed to promoting NEPA's faithful enforcement.

Amici Robert Glicksman, Oliver Houck, Daniel Mandelker, Thomas McGarity, Robert Percival, Zygmunt Plater, and Nicholas Robinson are law

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[1] Pursuant to Supreme Court Rule 37.3, the parties have consented to the filing of this brief, and letters of consent have been filed with the Clerk of this Court. Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for any party in this case authored this brief in whole or in part, and no person or entity other than *amici* and their counsel has made a monetary contribution to the preparation and submission of this brief.

[2] More detailed biographies of *amici* former General Counsels to CEQ are included in Appendix A.

professors from across the United States, each of whom has taught environmental, natural resources, and administrative law in excess of twenty years—in one case for over fifty years.[3] Their vast scholarship includes over two hundred law review articles, six casebooks, and the leading treatise on NEPA law. Although law professors often write about what law should be established, here they write to defend law that is already well-established.

SUMMARY OF ARGUMENT

District courts have broad discretion to tailor remedies to the circumstances of the case, and appellate courts should not, and historically have not, lightly cast aside the reasoned judgment made by the judge who has weighed the facts and balanced the equities first hand. Petitioners have not shown that the district court's findings of fact, taken largely from the administrative record, were clearly erroneous. Releasing Roundup Ready alfalfa into the environment without completing an environmental analysis would have exposed Respondents to a real and immediate threat of biological contamination, an environmental injury that is irreparable. Equitable relief does not require plaintiffs to show a near-certainty of irreparable harm, which amounts to a virtually impossible standard for future injuries. Indeed, courts have traditionally exercised their discretion to issue injunctions that avoid future harm where there is a real and immediate *threat* of harm.

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[3] More detailed biographies of *amici* law professors are included in Appendix A.

By enforcing the statutory procedures of the National Environmental Policy Act (NEPA), the district court respected the deliberately expressed judgment of Congress. As this Court recognized in *Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978), while equity courts enjoy broad discretion, that discretion does not extend so far as to give district courts authority to ignore a statute's principal objectives. Although the district court did not have an absolute duty to issue the injunction, the district court did not abuse its discretion by declining to issue the injunction proposed by the Animal and Plant Health Inspection Service (APHIS). After balancing the four equity factors, the remedy chosen by the district court preserved the opportunity for APHIS to comply with NEPA's twin aims of informed decisionmaking and public participation. Moreover, APHIS's proposed injunction would have undermined these two objectives by allowing APHIS to implement a decision first and then analyze it later.

ARGUMENT

Monsanto Company's petition to deregulate Roundup Ready alfalfa has not satisfied the procedural requirements Congress imposed before a potential "plant pest" can be released into the environment. In this case, the Plant Protection Act (PPA) defines the status quo: regulated plants, including genetically modified plants, cannot be released into the environment without a permit. 7 U.S.C. § 7712; 7 C.F.R. § 340.0(a)(2) n.1. Genetically modified plants can be deregulated, but a decision to deregulate must include an environmental analysis in compliance with NEPA, which requires agencies to disclose and analyze the full range of reasonably foreseeable environmental

impacts before implementing a decision that irreversibly or irretrievably commits resources to a course of action. 42 U.S.C. § 4332(2)(C); 7 C.F.R. § 372.5(b)(4). To comply with NEPA, APHIS's regulations require "early and adequate consideration of environmental factors in [APHIS's] planning and decisionmaking." 7 C.F.R. § 372.1.

Past examples of ecological devastation wrought by the unwitting introduction of plant and animal pests into the environment illustrate the wisdom of prohibiting the commercial sale and widespread distribution of genetically modified plants until APHIS finishes its NEPA analysis and concludes that the newly created plants are not "plant pests." *See* 7 U.S.C. § 7711(a); 7 C.F.R. § 340.0(a)(2) n.1. "There are reasons for believing [the experience with the introduction of non-native species] is pertinent to the assessment of risks associated with the deliberate release of organisms that have been modified by engineering." William H. Rodgers, Jr., *Rodgers' Environmental Law* § 6:12 (A) (Supp. 2009). Yet, Monsanto Company and its licensee Forage Genetics (collectively "Monsanto"), argue that the district court abused its discretion by rejecting a proposed injunction that would allow Roundup Ready alfalfa to be released into the environment on a commercial scale before APHIS finishes its NEPA analysis. However, APHIS's flawed NEPA analysis failed to analyze specific, threatened environmental harms, like biological contamination and the development of glyphosate-resistant weeds. Therefore, the district court's decision to preserve the status quo while APHIS corrected its errors was not an abuse of discretion.

I. THE DISTRICT COURT'S INJUNCTION BALANCED THE INTERESTS OF THE PARTIES WHILE ENFORCING THE PROCEDURAL REQUIREMENTS OF NEPA AND PPA.

The characteristics of flexibility and practicality allow courts in equity to tailor remedies to the circumstances of the individual case. *See Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944) ("Flexibility rather than rigidity" distinguishes equity jurisdiction.). Appellate courts do not lightly cast aside the factual findings or the equitable balances reached by district courts. They reject factual findings only where they are clearly erroneous and upset the balance struck by the district court only where there has been an abuse of discretion. *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006); *see Found. on Econ. Trends v. Heckler*, 756 F.2d 143, 151-52 (D.C. Cir. 1985). These standards of review are fundamental, and yet they are conspicuously absent from Petitioners' brief. Petitioners attempt to dodge these highly deferential standards by attacking the district court's decision on novel legal grounds, asserting error in the standard for irreparable harm and in the evidentiary procedures used by the district court. Though Petitioners disagree with the balance struck by the district court, they have not shown that the findings of fact, taken largely from the administrative record, were clearly erroneous. Nor have they shown that the balance reached, after the court carefully applied the traditional four-factor test and weighed the equities between the parties, was an abuse of discretion.

A. The risk of cross-contamination caused by releasing Roundup Ready alfalfa created a likelihood of irreparable harm that justified injunctive relief.

Injunctive relief, by definition, is forward-looking. *Douglas v. City of Jeanette*, 319 U.S. 157, 165 (1943). Thus, equity has traditionally sheltered plaintiffs from real threats of future wrongs that imperiled the plaintiffs' interests. *See, e.g., United Steelworkers of Am. v. United States*, 361 U.S. 39, 40-42 (1959) (enjoining strike because, if the strike continued, it would create further delay in steel production, and delay would imperil national health and safety); 42 Am. Jur. 2d *Injunctions* § 2 (Supp. 2010) ("Injunctive relief is designed to meet a real threat of a future wrong or a contemporary wrong of a nature likely to continue or recur."); *see also O'Shea v. Littleton*, 414 U.S. 488, 496 (1974) ("[P]ast wrongs are evidence bearing on whether there is a real and immediate threat . . . .").

Though equity sometimes remedies present harm, its principal remedial effect is prospective, guarding against future harm despite the future's inherent uncertainty. *See United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953) ("The purpose of an injunction is to prevent future violations . . . ."); *United States v. Or. State Med. Soc'y*, 343 U.S. 326, 333 (1952) ("The sole function of an action for injunction is to forestall future violations."). Equitable relief has guarded a village against dam failure, obtained treatment for orphans at risk for neurological illness, and even ensured that the Seattle Supersonics had their star basketball player, Spencer Haywood, for the

upcoming NBA playoffs. *See Warm Springs Dam Task Force v. Gribble*, 417 U.S. 1301 (Douglas, Circuit Justice 1974); *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984); *Haywood v. NBA*, 401 U.S. 1204 (Douglas, Circuit Justice 1971), respectively.

The extent to which the threat of future harm imperils the plaintiff's interest, i.e., the significance of the risk, has always been a question for the trial court's equitable discretion. For example, commentators agree that a lower probability of an extremely grave irreparable harm may entitle a plaintiff to injunctive relief where the same probability of a more minor irreparable harm would not. *See* 11A Charles Allen Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2948 (2d ed. 1982) (courts should consider "the *significance* of the threat of irreparable harm" (emphasis added)); *see generally* Restatement (Second) of Torts § 933(1) (1979), cmt. b ("The more serious the impending harm, the less justification there is for taking the chances that are involved in pronouncing the harm too remote."); Cass R. Sunstein, *Irreversible and Catastrophic*, 91 Cornell L. Rev. 841, 870 (2006) (noting that a one-in-a-million chance that 200 million people will die and a fifty-fifty chance that 400 people will die both create an expected cost of 200 lives).

Risk is not harmless simply because the threat of harm is not certain. *See United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (establishing B<PL test for negligence liability that considered the probability of future harm, i.e., risk). This Court noted over one hundred years ago that federal courts can use their equitable powers to "prevent nuisances that are threatened, and before

irreparable mischief ensues . . . and, by perpetual injunction, protect the public against them in the future." *Mugler v. Kansas*, 123 U.S. 623, 673 (1887). The law of anticipatory nuisance, for instance, offers relief from prospective harm caused by a future nuisance, even in the absence of past or present injury. Plaintiffs need not prove they have already been harmed, because "even threatened harm is actionable under the federal common law of nuisance." *Connecticut v. Am. Elec. Power*, 582 F.3d 309, 357 (2d Cir. 2009).

In light of this precedent, it was hardly novel, much less an abuse of discretion, for the district court to issue an injunction guarding against the future irreparable harm of biological contamination where the record established that the risk was "sufficiently likely." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987). Indeed, the facts before the district court showed that this standard had been surpassed because biological contamination had already occurred. Pet.App. 13a, 61a. As the district court explained, biological contamination from cross-pollination between Roundup Ready alfalfa and organic alfalfa is irreparable because "[t]he contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa. Moreover, it is not a one season loss; alfalfa is a perennial crop and once removed cannot be replanted for two to four years." Pet.App. 71a. Once a conventional alfalfa farmer's seed crop is contaminated, "there is no way for the farmer to remove the gene from the crop or control its further spread." Pet.App. 36a. Therefore, Judge Breyer's conclusion that irreversible genetic

contamination of conventional alfalfa crops was irreparable harm was not clearly erroneous.

In addition to confirming irreparable harm, the record amply supports Judge Breyer's finding that biological contamination could occur, establishing a "likelihood" of irreparable injury. It is undisputed that cross-contamination could occur, and has occurred. Pet.App. 61a ("APHIS acknowledged that gene transmission could and had occurred with Roundup Ready alfalfa."). APHIS's environmental assessment acknowledged this risk and even analyzed the possibility that gene transmission could eradicate all other strains of alfalfa. Pet.App. 42a-43a.[4] It is also undisputed that glyphosate-resistant weeds could develop. Pet.App. 45a-46a. Finally, it is undisputed that Roundup Ready alfalfa has been made commercially available and that, absent an injunction, its use would increase. *See* Pet.App. 64a. In addition to these undisputed facts, the district court made further factual findings. "[G]ene transmission is *especially likely* in this context given the geographic concentration of alfalfa seed production." Pet.App. 35a-36a (emphasis added). Thus, the district court's

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[4] Petitioners take issue with the district court's "suggestion that continued planting of [Roundup Ready alfalfa] could eliminate the availability of conventional alfalfa." Pet. Br. 34. This "suggestion," however, came from APHIS, not from the district court. The possibility that gene transmission could eliminate the ability to grow non-genetically engineered alfalfa is the reason that APHIS analyzed the economic impacts that elimination of organic or conventional alfalfa crops would have on farmers. Pet.App. 44a-45a. Additionally, an internal APHIS email acknowledged that "it may be hard to guarantee that seeds or sprouts are GE free." Pet.App. 38a.

conclusion that cross-contamination was sufficiently likely was not clearly erroneous.

Though the record demonstrates that the district court found a likelihood, not just a possibility, of irreparable harm, Petitioners attack the court's legal standard for irreparable harm by distorting the language of the court's order. Throughout their brief, Petitioners suggest that the district court's use of the phrase "sufficiently likely" indicates that the court applied an inappropriate "mere 'possibility'" standard. Pet. Br. 19, 21, 41, 44. Yet "sufficiently likely" is neither a lenient standard imposed by the Ninth Circuit nor a radical invention of the district court: it was this Court's own description of the proper standard for the issuance of an injunction. *See Amoco,* 480 U.S. at 545 ("If such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment."). Nowhere did the district court suggest that the mere possibility of cross-pollination entitled the plaintiffs to an injunction. If the court had applied a possibility standard, it would not have needed a ten-page memorandum to explain the justification for its permanent injunction; a short order citing to APHIS's environmental assessment—record evidence that acknowledges (at a minimum) the *possibility* of gene transmission—would have sufficed. Pet.App. 45a. Instead, the district court went much further, weighing the facts and concluding that, in light of the close geographic distribution of alfalfa crops and the fact that gene transmission had already occurred, biological contamination was sufficiently likely to occur under APHIS's proposed injunction. *See, e.g.*, Pet.App. 61a, 70a, 71a; Pet.App. 10a, 13a.

The Petitioners' misguided articulation of the "likelihood" of irreparable harm standard stems from their misreading of this Court's opinion in *Winter v. Natural Resources Defense Council*, 129 S. Ct. 365 (2008), which they claim requires a near-certainty of irreparable harm—a standard that would make a forward-looking injunction nearly impossible. This Court has never countenanced such a standard. Indeed, although this Court has characterized the likelihood standard slightly differently over the years, the standard itself has never changed; it remains part of the same equitable balancing test "historically employed by courts of equity." *eBay*, 547 U.S. at 390. *Compare Winter*, 129 S. Ct. at 375 ("*likely*"), *with Amoco*, 480 U.S. at 545 ("sufficiently likely"), *with City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983) ("likelihood"), *and O'Shea*, 414 U.S. at 502 (same), *with W. T. Grant*, 345 U.S. at 633 ("cognizable danger . . . something more than the mere possibility").

Equity has never required a showing that irreparable harm is more likely than not, and Petitioners cite no case establishing such a bright line. Several federal courts of appeals have interpreted this Court's various descriptions of "likelihood" to mean "significant risk," but there is no fixed line separating significant risks from speculative ones. *See Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250, 1258 (10th Cir. 2003) ("[A]n injury is not speculative simply because it is not certain to occur."); *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000) ("The irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by monetary damages."):

Assoc. Gen. Contractors of Cal., Inc. v. Coal. for Econ. Equity, 950 F.2d 1401, 1410 (9th Cir. 1991) ("[T]he party seeking the injunction must demonstrate that it will be exposed to some significant risk of irreparable injury.").

B. A new and unanalyzed activity can create a sufficient likelihood of irreparable harm.

The district court did not abuse its discretion by rejecting an injunction that would have radically altered the status quo before APHIS completed the environmental analysis. APHIS's proposed injunctive relief would have authorized exponential expansion of Roundup Ready alfalfa production nationwide, increasing the number of acres planted by five-fold in less than a year. Pet.App. 64a. The district court properly refused to endorse such dramatic growth of a new and unanalyzed activity, especially when it found biological contamination had already occurred under planting conditions similar to those proposed in APHIS's injunction. Pet.App. 70a. Neither information gathered through analysis nor experience supports APHIS's assertion that its injunctive measures would avoid biological contamination.

A court is well within its equitable discretion to enjoin an unprecedented activity from proceeding until after a proper environmental analysis, required by statute, has been conducted. *See Found. on Econ. Trends*, 756 F.2d at 157. In *Sierra Club v. Marsh*, then-Judge, now-Justice, Breyer noted that the "added *risk* to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with prior

public comment) of the likely effects of their decision upon the environment" can create irreparable harm. 872 F.2d 497, 500 (1st Cir. 1989); *see also Massachusetts v. Watt*, 716 F.2d 946, 952 (1st Cir. 1983) (Breyer, J.).

In *Foundation on Economic Trends*, the D.C. Circuit upheld an injunction stopping the National Institute of Health (NIH) from releasing new genetically engineered bacteria into the environment until after it completed an adequate NEPA analysis. 756 F.2d at 150. With reasoning remarkably similar to that advanced by Petitioners in this case, NIH acknowledged that the engineered bacteria could multiply and disperse throughout the environment, but argued that the likelihood of dispersion was low and, therefore, did not analyze whether dispersion would cause environmental injury. *Id.* at 153. Due to NIH's "complete failure to address a major environmental concern" before authorizing an unprecedented activity that threatened environmental harm, *id.* at 154, the D.C. Circuit upheld the injunction delaying the proposed experiment.[5] In contrast, in *Winter*,

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[5] The district court actually enjoined two activities: (1) a specific approval of the deliberate release of genetically modified organisms; and (2) a policy change authorizing direct release experiments. The D.C. Circuit upheld the injunction regarding the first activity, but concluded that the second injunction was "overly broad" in part because the regulations did not make direct release "an imminent possibility." *Found. on Econ. Trends*, 756 F.2d at 158. This result reflects the power of equity courts to shape a remedy that can fulfill the objectives of NEPA without adversely affecting society by issuing an overly broad injunction. *See Wisconsin v. Weinberger*, 745 F.2d 412, 426 (7th Cir. 1984) (where NEPA violation was uncertain, and the only threatened

experience weighed against the issuance of an injunction where the Navy had not yet done a NEPA analysis for training exercises that had been "taking place in SOCAL for the last 40 years." *See Winter*, 129 S. Ct. at 376. In declining to issue an injunction, this Court found it "pertinent" that the Navy was not "conducting a new type of activity with completely unknown effects on the environment." *Id.*

In this case, Petitioners cannot rely on either analysis or experience to demonstrate that APHIS's proposed injunction would truly guard against irreparable biological contamination. Pet.App. 69a-70a ("[Defendants] have not submitted any evidence that suggests whether, and to what extent, the proposed interim conditions will be followed, even though such conditions are similar to those already imposed by Forage Genetics in its contracts with Roundup Ready seed growers and contamination has occurred despite these conditions.").

This is not a case where the lack of information is an injury that is suffered by all and so actionable by none. *Cf. Allen v. Wright*, 468 U.S. 737, 751, 760 (1984) (summarizing prior line of cases as representing the principle that "absent an allegation of a specific threat of being subject to the challenged practices, plaintiffs had no standing to ask for an injunction"). To the contrary, traditional seed farmers need the information missing from the environmental assessment to protect their crops from biological contamination—even if Roundup Ready alfalfa is only partially deregulated. APHIS summarily concluded that biological

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injury was agency preference for a particular course of action, an injunction was unwarranted).

contamination was "highly unlikely" if growers used "quality control," but the agency did not explain or identify any quality control measures that would prevent gene transmission between neighboring seed farms, nor did it analyze the burden that such measures would impose on farmers of conventional alfalfa. Pet.App. 31a, 41a. The informational injury here is particularized and consequential, and it created a sufficient likelihood of irreparable harm. Therefore, the district court did not abuse its discretion by delaying APHIS's foray into "uncharted territory," Pet.App. 45a, by requiring APHIS to finish a meaningful NEPA analysis before deregulating Roundup Ready alfalfa.

C. The district court thoroughly balanced the equities in accordance with the traditional four-part test for injunctive relief.

Petitioners' assertion that the district court applied a "special rule" for NEPA cases instead of balancing the four traditional factors is not supported by the court's decision. As discussed thoroughly above, Judge Breyer concluded that the risk of biological contamination caused by increasing the amount of Roundup Ready alfalfa in the environment created a sufficiently likely threat of irreparable harm. Judge Breyer found that the balance of hardships favored issuing an injunction because any harm to Monsanto would be purely economic and would "not outweigh the potential irreparable damage to the environment." Pet.App. 72a (internal citation omitted). Additionally, in light of NEPA's statutory purpose, Judge Breyer found it "in the public interest to delay the further

introduction of Roundup Ready alfalfa into the environment while APHIS studies the environmental consequences of such action." Pet.App. 75a. Finally, he explicitly concluded that "plaintiffs have sufficiently established irreparable injury and that the balance of the equities weighs in favor of maintenance of the status quo and against allowing the continued expansion" of Roundup Ready alfalfa during completion of the EIS. Pet.App. 71a.

As the arbiter who placed the weights upon the scales, Judge Breyer was best positioned to eye the balance. His judgment was not an abuse of discretion, and is, therefore, entitled to deference. *See eBay*, 547 U.S. at 391.

II. THE DISTRICT COURT'S INJUNCTION RESPECTED THE WILL OF CONGRESS BY ENFORCING NEPA'S STATUTORY PROCEDURES AND POLICIES.

Although courts in equity have broad discretion to fashion a remedy, their discretion is not so broad that they can refuse to enforce a statutory scheme. The choice before courts sitting in equity is "whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497-98 (2001). "[A] court sitting in equity cannot 'ignore the judgment of Congress, deliberately expressed in legislation.'" *Id.* at 497 (quoting *Virginian Ry. Co. v. Sys. Fed'n No. 40*, 300 U.S. 515, 551 (1937)). Although district courts enjoy "sound discretion" to tailor injunctive relief to the "necessities of the public interest," in the statutory

context, Congress defines the public interest. *Hecht Co. v. Bowles*, 321 U.S. 321, 329-31 (1944).[6] These principles do not change when applied to NEPA.

With NEPA, Congress prioritized foresight, planning, and analysis as antidotes to "new and expanding technological advances" that could profoundly affect the environment. 42 U.S.C. § 4331(a). "Once Congress . . . has decided the order of priorities in a given area, it is for the Executive to administer the

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[6] To be sure, there are cases in which this Court has concluded that a statutory violation did not require an injunction. *See, e.g., Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982); *Hecht Co. v. Bowles*, 321 U.S. 321 (1944). However, these cases illustrate, rather than undermine, the strength of the principle that courts exercise their equitable discretion in light of the large objectives of the statutory scheme and do not have discretion to authorize behavior that Congress intended to prohibit. *See generally* Zygmunt B. Plater, *Statutory Violations and Equitable Discretion*, 70 Cal. L. Rev. 524, *passim* (1982). In *Amoco*, the large objectives of the statute were designed to protect subsistence resources, and the district court expressly found that exploration activities would not significantly restrict subsistence uses. 480 U.S. at 544. Therefore, an injunction requiring statutory compliance was not required. Similarly, in *Weinberger*, this Court concluded that the Navy's training sessions off the coast of Puerto Rico, resulting in "accidental bombings of the navigable waters," did not undermine the statutory purpose of the Clean Water Act because "the discharge of ordnance had not polluted the waters." 456 U.S. at 307, 315. Therefore, "[a]n injunction [was] not the only means of ensuring compliance" with the large objectives of the Clean Water Act. *Id.* at 314. Finally, in *Hecht*, this Court concluded that an injunction was not mandatory because statutory compliance was already assured. 321 U.S. at 326. In this case, however, as explained more thoroughly in this section, the district court could not have entered APHIS's proposed injunction and still have fulfilled the statutory objectives of NEPA: informed decisionmaking and public participation.

laws and for courts to enforce them when enforcement is sought." *TVA v. Hill*, 437 U.S. 153, 194 (1978). APHIS's proposed injunction would have overridden the procedural safeguards that Congress imposed through NEPA against rash decisions that could have significant environmental impacts. *See* 42 U.S.C. § 4332(2)(C). Therefore, the district court did not abuse its discretion when it rejected APHIS's proposal and chose to enforce NEPA's procedures.[7]

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[7] Petitioners argue that NEPA's statutory objectives only protect "the environment" and "absent species-level harm there is no meaningful change in the environment." Pet. Br. 36-37. This argument is fundamentally flawed. Congress specifically referenced localized harms by requiring environmental impact statements to include "the relationship between *local short-term uses* of man's environment and the maintenance and enhancement of long-term productivity." 42 U.S.C. § 4332(2)(C)(iv) (emphasis added). Petitioners' argument also ignores the fact that NEPA contextualizes the significance of environmental impacts. 40 C.F.R. § 1508.27(a) ("[T]he significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality.").

Petitioners are also wrong to suggest that NEPA's statutory objectives only protect the environment, not individuals or people. Prior to the final passage of NEPA, Senator Jackson, one of NEPA's chief sponsors, articulated the relationship between humans and the environment from the Senate floor. "An environmental policy is a policy for people. Its primary concern is with man and his future." 115 Cong. Rec. 40,416 (1969). Congress's declaration of national environmental policy supports Senator Jackson's statement. *See, e.g.*, 42 U.S.C. § 4331(c) (declaring that "*each person* should enjoy a healthful environment" (emphasis added)); *id.* § 4331(b)(4) (stating that NEPA protects "an environment which supports diversity and variety of *individual* choice" (emphasis added)).

"A court must exercise this [equitable discretion] 'in light of the large objectives of the Act.'" *Albemarle Paper Co. v. Moody*, 422 U.S. 405, 416 (1975) (quoting *Hecht*, 321 U.S. at 331). This Court has described NEPA's large objectives as the twin aims of informed decisionmaking and public participation. *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 768 (2004); *Balt. Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 97 (1983). Neither of these objectives would be satisfied by APHIS's proposed injunction, which would have timed the NEPA analysis to postdate the release of Roundup Ready alfalfa, authorized an uninformed agency decision, and substituted an evidentiary hearing for NEPA's public process. Had the district court allowed APHIS to shunt NEPA's procedures to the side, to be accomplished in the aftermath of a decision made—and implemented—it would have abused its discretion by adopting a remedy that undermined the procedural scheme Congress adopted to achieve NEPA's large objectives and would have substituted the "chancellor's clumsy foot for the rule of law." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 335 (1982) (Stevens, J., dissenting).

A. To inform decisionmaking, a NEPA analysis must be conducted before the decision is implemented.

The difference between the injunction that the district court adopted and the injunction APHIS proposed was timing: and timing is critical to enforcing NEPA's large objectives. The district court's injunction insured that the agency's NEPA analysis would *precede* the widespread, commercial dissemination of Roundup Ready alfalfa; while under APHIS's injunction, the

analysis would have *postdated* the release. The difference in timing between these two injunctions is the difference between enforcing and not enforcing NEPA's objectives, where the unanalyzed activity threatened environmental injury. APHIS's proposed injunction would have allowed the "continued and dramatic growth of the Roundup Ready alfalfa market." Pet.App. 64a. It could have authorized a five-fold increase in acreage planted before APHIS had gathered the missing information about how (and whether) biological contamination could be avoided. Pet.App. 64a. In other words, APHIS's injunction would have allowed the agency to implement a decision and analyze it later.

Because this approach stands NEPA on its head, the district court was well within its discretion to issue an injunction. Under NEPA, agencies must include a "detailed statement" on the environmental impacts of every *proposed* (not implemented) action significantly affecting the quality of the human environment and compile a description of adverse environmental impacts that cannot be avoided *if* the proposal is implemented. 42 U.S.C. § 4332(2)(C); *see* 40 C.F.R. § 1500.1(b). NEPA is not about data gathering for the sake of gathering data; rather, it should inform a proposed agency action. Environmental impact statements should be useful analytic documents that promote informed decisionmaking, not tomes filled with information, gathering dust on a shelf. *See* 40 C.F.R. § 1502.2(a) ("Environmental impact statements shall be analytic rather than encyclopedic."). NEPA is all

about informed decisionmaking. To accomplish this purpose, the process must precede the decision.[8]

The district court's injunction also preserved APHIS's ability to choose among reasonable alternatives prior to taking action on Monsanto's request for deregulation. 40 C.F.R. § 1502.14 (agencies should "[r]igorously explore and objectively evaluate" all reasonable alternatives including a "no action" alternative). In contrast, like squeezing a tube of toothpaste, APHIS's injunction would have foreclosed the "no action" alternative by releasing Roundup Ready alfalfa into the environment without a viable means of re-containing it. If the court had authorized APHIS's approach, it would have foreclosed the critical "no action" alternative of not deregulating at all, thereby allowing the agency to commit resources to a course of action before it completed its NEPA analysis. *See* 40 C.F.R. § 1502.2(f) ("Agencies shall not commit resources prejudicing selection of alternatives before

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[8] Of course, that does not mean that an injunction must issue in every NEPA case in which there is an analytical flaw. "The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as a chancellor is not mechanically obligated to grant an injunction for every violation of law." *Weinberger*, 456 U.S. at 313. Whether the agency can still make an informed decision despite a NEPA violation is a fact-specific inquiry better suited to individual cases rather than broad generalizations. NEPA's procedural requirements "'ensur[e] that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning significant environmental impacts.'" *Winter*, 129 S. Ct. at 376 (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989)).

making a final decision."); *see also id.* § 1506.1(a)(2) ("Until an agency issues a record of decision . . . no action concerning the proposal shall be taken which would . . . [l]imit the choice of reasonable alternatives."). .

The bottom line is this: NEPA documents should not justify decisions already made. *Id.* § 1502.2(g). But that is precisely what APHIS's EIS would have done if the district court had adopted an injunction allowing further release of Roundup Ready alfalfa into the environment before the EIS was completed.

By rejecting APHIS's injunction, and prohibiting further Roundup Ready alfalfa plantings or sales, the district court preserved the opportunity for APHIS to comply with NEPA, and thereby required APHIS to "abide by the limitations prescribed by the Legislature." *Wilderness Soc'y v. Morton*, 479 F.2d 842, 892 (D.C. Cir. 1973).

B. APHIS's proposed injunction would have undermined NEPA's requirement that environmental analyses inform agency decisions.

The complete deregulation of Roundup Ready alfalfa will destroy the livelihoods of conventional and organic alfalfa farmers and generate Roundup-resistant superweeds. *See* JA 109, 111, 135 (comments submitted to APHIS); *see* JA 678-79 (declaration).

The complete deregulation of Roundup Ready alfalfa will create a negligible risk of cross-pollination and will have no significant impact on the emergence of Roundup-resistant superweeds. *See* Pet.App. 160a, 401a (declarations).

The respective accuracy of each of these over-simplified positions (and all possibilities in between) is unknown because APHIS's NEPA analysis failed to take a hard look at these and other potentially irreversible environmental impacts *prior* to deregulating Roundup Ready alfalfa. Without understanding the environmental impacts that threatened environmental harm, APHIS could not make an informed decision about releasing Roundup Ready alfalfa.

NEPA requires informed decisionmaking. Agencies must, "to the fullest extent possible," systematically integrate the natural and social sciences in planning and in decisionmaking. 42 U.S.C. § 4332(2)(A). However, here, numerous aspects of APHIS's environmental assessment revealed foreseeable, but unanalyzed, impacts that threatened environmental harm. For example, APHIS never analyzed the cumulative impact caused by a dramatic increase in the use of glyphosate as a fertilizer and the consequent possibility that Roundup-resistant weeds could develop. Pet.App. 47a. As the district court noted, other Roundup Ready crops, including corn and soybeans, have already been deregulated and more deregulation petitions are pending. Pet.App. 47a. Alfalfa is the fourth largest crop in the United States, the first large-scale perennial Roundup Ready crop, and the first crop in which APHIS acknowledged on the record that there is a chance of gene transmission. Pet.App. 27a, 45a, 47a. Adding it to the mix may have significant consequences for the quality of the human environment. Pet.App. 45a. Failure to investigate these cumulative impacts violated Congress's mandate that "all agencies of the Federal Government shall . . .

[identify] the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity." 42 U.S.C. § 4332(2)(C)(iv).

APHIS also failed to analyze impacts on organic farmers, on export markets, and on the availability of non-genetically modified alfalfa. NEPA protects "historic, cultural and natural aspects of our national heritage," as well as "an environment which supports diversity and variety of individual choice." 42 U.S.C. § 4331(b)(4). A federal action "that eliminates a farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food," Pet.App. 44a, should have been thoroughly analyzed, particularly where it threatens environmental injury. In furtherance of Congress's policies set out in NEPA, APHIS must analyze these impacts before authorizing the planting of one million acres of Roundup Ready alfalfa.

Reviewing courts should base their decisions on the administrative record and should not substitute their judgment for that of the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Where the administrative record is silent, district courts properly remand, rather than conduct fact-finding procedures in the first instance. As Chief Judge Friendly once noted, "preservation of the integrity of NEPA necessitates that the [agency] be required to follow the steps set forth in § 102 [42 U.S.C. § 4332], even if it now seems likely that those steps will lead it to adhere to the present result." *City of New York v. United States*, 337 F. Supp. 150, 160 (E.D.N.Y. 1972). To do otherwise would shortcut the process that Congress committed in the first instance to the

responsible federal agency. *Jones v. Lynn*, 477 F.2d 885, 891-92 (1st Cir. 1973).

The district court properly recognized this principle when it refused to render an independent judgment about whether APHIS's proposed conditions, not analyzed in the environmental assessment, eliminated the likelihood of environmental injury caused by cross-contamination. Pet.App. 67a. "To make the findings requested by defendants would require this Court to engage in precisely the same inquiry it concluded APHIS failed to do . . . without the benefit of all the relevant data and, importantly, without the opportunity for and consideration of public comment." Pet.App. 68a. Far from violating due process, Pet. Br. 51, this approach respected Congress's unequivocal dictate that "the policies, regulations, and public laws of the United States *shall* be interpreted and administered in accordance with policies set forth in this chapter." 42 U.S.C. § 4332 (emphasis added).

Where, as here, the agency has failed to make an informed decision pursuant to NEPA's procedures, district courts cannot make up for the lapse by conducting an evidentiary hearing, as requested by Petitioners, and by deciding in the first instance the desirability of the proposed action. Far from an abuse of discretion, the judicial restraint exercised by the district court protected "the integrity of the fact-finding process mandated by Congress in 42 U.S.C. § 4332(2)(C)." *Jones*, 477 F.2d at 892.

C. Conducting an evidentiary hearing to decide whether Roundup Ready alfalfa should be released without a NEPA analysis would have undermined NEPA's aim of public participation.

The affidavits of experts proffered by APHIS and Monsanto on the effectiveness of APHIS's proposed injunctive measures cannot remedy APHIS's failure to analyze whether biological contamination was avoidable, as NEPA requires. *See* Pet.App. 66a-67a. "NEPA procedures must insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken." 40 C.F.R. § 1500.1(b); *see also id.* § 1501.1(a); *Dep't of Transp.*, 541 U.S. at 768 (Agencies must "have available, and . . . carefully consider, detailed information concerning significant environmental impacts" *prior* to taking any major federal action.). Monsanto and APHIS gathered the expert affidavits after APHIS made its deregulation decision, so they were divorced from the other features of a NEPA analysis, like the requirement to "study, develop, and describe appropriate alternatives . . . in any proposal which involves unresolved conflicts." 40 C.F.R. § 1501.2(c).

The restrictions in APHIS's proposed injunction, based on expert affidavits, were not made available to the public. 40 C.F.R. § 1500.1(b). Because the experts' affidavits were no substitute for the NEPA process, the district court properly rejected Monsanto's argument that these affidavits could change the balance of equities. Where Congress has established the public interest, as articulated in a statute's large objectives, courts should enforce that judgment, "[f]or the

standards of the public interest not the requirements of private litigation measure the propriety and need for injunctive relief." *See Hecht*, 321 U.S. at 331.

By prohibiting further sale and distribution of Roundup Ready alfalfa, the district court followed Congress's directive that the "policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with [NEPA]." 42 U.S.C. § 4332. This decision, far from an abuse of discretion, respected the priorities expressed by Congress in NEPA. *See TVA*, 437 U.S. at 194.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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April, 2010

Appendix A

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Gary Widman served as the General Counsel to the CEQ in the administrations of Presidents Nixon and Ford, from 1974 through 1976. Before and after his time at CEQ, he was a Professor of Law at the University of California, Hastings College of the Law. He also served as Associate Solicitor for Conservation and Wildlife in the Department of the Interior during the Carter administration, as counsel to the Washington, D.C. office of the Fulbright & Jaworski law firm, as Director of the Office of Staff Attorneys for the U.S. Court of Appeals for the Ninth Circuit from

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Thomas McGarity is the Joe R. and Teresa Lozano Long Endowed Chair in Administrative Law at the University of Texas at Austin School of Law, teaching in the fields of administrative law, environmental law, food safety law, and torts. In these and related fields, he has published over seventy articles and authored or co-authored eight books, including *Bending Science: How Special Interests Corrupt Public Health Research* (co-author); *The Law of Environmental Protection* (co-author); and *Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy*.

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Nicholas Robinson is the Pace University Professor on the Environment and the Gilbert and Sarah Kerlin Distinguished Professor of Environmental Law at Pace University School of Law as well as Co-Director for that law school's Center for Environmental Legal Studies. He teaches in the fields of environmental and historic preservation law. He participated in the development of NEPA regulations as a Member of the Legal Advisory Committee to the President's Council on Environmental Quality from 1970 to 1972, advising CEQ on the implementation of NEPA, after it was first adopted. He has published numerous books, chapters, and scholarly articles on environmental, energy, international, and land use law, including *Climate Change Law: Mitigation and*

Adaptation (co-author) and *New York Environmental Law: A Legal Treatise*. He has advised and represented governments and drafted treaties and laws on environmental issues at the international, state, and municipal levels. From 1983 to 1985, he served as Deputy Commissioner and General Counsel to the New York State Department of Environmental Conservation, advising New York on its compliance with NEPA and revising the regulations for New York's Environmental Quality Review Act (New York's "Little NEPA").

AMICUS CURIAE BRIEF

Supreme Court, U.S
FILED
MAR 8 - 2010
OFFICE OF THE CLERK

No. 09-475

B25848

IN THE

Supreme Court of the United States

MONSANTO COMPANY, ET AL.,
Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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BRIEF OF *AMICI CURIAE* CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN PETROLEUM INSTITUTE, NATIONAL ASSOCIATION OF HOME BUILDERS, AND CROPLIFE AMERICA IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici are trade associations that represent companies affected by the National Environmental Policy Act ("NEPA").[1] In particular, *Amici*'s members often depend on federal action to implement private initiatives ranging from building houses to oil exploration and production to selling fertilizers and other products. But the predicate federal action—and any resulting private initiative—cannot go forward until the environmental review required by NEPA is complete. In addition, as this case evidences, NEPA litigation often further delays (and sometimes effectively kills) important federal action and related private initiatives. Accordingly, *Amici* have a vital interest in the development of policy and law related to NEPA.

Amicus the Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interest of its members in matters before Congress, the Executive Branch,

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[1] Counsel of record for Petitioners filed a blanket consent to the participation of *amici curiae* with the Court. Respondents, through their counsel of record, consented to the filing of this brief, and their consent has been filed with the Court. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* made a monetary contribution to its preparation or submission.

and the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.

The Chamber has been active in shaping NEPA law and policy. The Chamber currently is promoting changes that would modernize NEPA by streamlining the environmental review process. The Chamber also recently championed a provision in the American Recovery and Reinvestment Act of 2009 ("ARRA") requiring that "[a]dequate resources" be devoted to ensuring NEPA environmental reviews of stimulus projects are completed on an "expeditious basis" and that "the shortest existing applicable process" under NEPA is utilized. Title XVI, § 1609(b). Finally, the Chamber has raised public awareness of the costs associated with NEPA litigation. For example, the Chamber maintains a website (http://pnp.uschamber.com) that tells the story of how hundreds of energy projects—and "green jobs" that go with them—have been stalled or killed through litigation under NEPA and other environmental statutes.

Amicus the American Petroleum Institute ("API") is a nationwide trade association headquartered in Washington, D.C., that represents over 400 members engaged in all aspects of the petroleum and natural gas industry, including exploration, production, transportation, refining, and marketing. API's members are affected by NEPA when, for example, their oil exploration and production activities occur on federal land or require federal action under statutes such as the Endangered Species Act ("ESA") and the Marine Mammal Protection Act.

Amicus the National Association of Home Builders ("NAHB") represents over 175,000 builder and associate members throughout the United States, including individuals and firms that construct and supply single-family homes, as well as apartment, condominium, multi-family, commercial and industrial builders, land developers, and remodelers. As part of the construction and development process, NAHB's members are affected by NEPA when they obtain federal approvals under statutes such as the Clean Water Act ("CWA") and the ESA. NAHB frequently participates as a party litigant and *amicus curiae* to safeguard the rights and interests of its members. For example, NAHB was a petitioner in a CWA case, *NAHB v. Defenders of Wildlife*, 127 S. Ct. 2518 (2007), and participated as *amicus curiae* in the Court's most recent NEPA case, *Winter v. Natural Resources Defense Council*, 129 S. Ct. 365 (2008).

Amicus CropLife America ("CLA"), which was organized in 1933, is the nationwide not-for-profit trade organization representing the major manufacturers, formulators, and distributors of crop protection and pest control products. CLA is headquartered in Washington, D.C. Its member companies produce, sell, and distribute most of the active compounds used in crop protection products registered for use in the United States. CLA represents its members' interests by, *inter alia*, monitoring federal agency regulations and agency actions and related litigation to identify issues of concern to the crop protection and pest control industry, and participating in such actions when appropriate. CLA participated as *amicus curiae* in *Winter*.

Amici file this brief to respectfully urge the Court to reject the holding below that, in NEPA cases in which further environmental review is ordered, it is not the district court's "job" to determine likely irreparable harm before granting an injunction. *Amici* urge the Court to reaffirm yet again that a district court must find, *inter alia*, likely irreparable harm before granting injunctive relief in every case, including a case brought under NEPA.

SUMMARY OF ARGUMENT

This Court repeatedly has admonished that granting injunctive relief is an extraordinary exercise of judicial power that is only justified when necessary to avoid likely irreparable harm. Nevertheless, lower courts—like the district court and Ninth Circuit here—continue to create exceptions to this command. In this case, the Court should make clear once and for all that a court must find likely irreparable harm before issuing an injunction.

NEPA cases are not excepted from this Court's requirements or equity's strict demands regarding injunctive relief. To the contrary, requiring a threshold showing of likely irreparable harm before granting injunctive relief is particularly important in NEPA cases. Although NEPA is a procedural statute that mandates no "particular results," NEPA nevertheless has enormous substantive implications on federal and private projects and thus the economy. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350, 353 n.16 (1989). The requisite environmental review under NEPA often takes years (sometimes more than a decade) to

complete, only to be followed by a lawsuit second-guessing the agency's compliance with NEPA. In almost half of NEPA cases, the courts find that the agency somehow tripped over NEPA's notoriously vague commands and thus order yet further environmental review.

Contrary to the decisions below, once a district court perceives an error under NEPA, it is precisely the district court's "job" to weigh the evidence and determine whether there likely will be irreparable harm to the environment absent the injunction. By instead punting that inquiry, the decisions below make injunctive relief a foregone conclusion—not an extraordinary remedy—in NEPA cases. The end result is that important federal actions and related private initiatives will be *further* delayed pending completion of environmental reviews, regardless of whether the underlying federal actions pose any likelihood of irreparable harm to the environment. This turns the equitable principles governing injunctive relief on their head and transforms a procedural statute into a mechanism for paralysis of substantive federal and private action.

By removing the discipline of finding irreparable harm before issuing an injunction, the decisions below also grant district judges extraordinary power to halt federal and private projects with which they disagree as a matter of policy. At the same time, they leave no room for deference to the agency on whether something short of complete injunctive relief is sufficient to prevent irreparable harm. Such deference is particularly appropriate where, as in this case, the question of irreparable harm is within the scientific expertise of the agency and the agency

has extensive experience relevant to that question. The Ninth Circuit's decision, which deferred to the district court and not the agency, should be reversed.

BACKGROUND

To understand the far-reaching and dangerous implications of the decisions below, it is important to understand how NEPA operates and the practical implications it has for federal and private actions.

I. AGENCY REVIEW UNDER NEPA

NEPA's core mandate requires federal agencies to prepare an environmental impact statement ("EIS") for "every . . . major Federal action[ ] significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). To comply with this mandate, federal agencies generally take one of three actions. First, an agency may make a "categorical exclusion" ("CE") determination if (1) the action falls within a category that has been determined, based on prior experience and analysis, to not cause a significant impact and (2) no extraordinary circumstances exist that might cause a significant impact in the specific case. In the case of a CE, the agency documents the CE determination, but does not prepare an environmental assessment ("EA") or EIS. 40 C.F.R. § 1508.4.

Second, absent a CE determination, the agency prepares an EA, which is a "concise public document" that provides "sufficient evidence and analysis for determining" whether to prepare an EIS. 40 C.F.R. § 1508.9(a)(1). "If the EA leads the agency to conclude that the proposed action will not significantly affect

the environment, the agency may issue a finding of no significant impact ('FONSI') and forego the further step of preparing an EIS." *Greater Yellowstone Coal. v. Flowers*, 359 F.3d 1257, 1274 (10th Cir. 2004). But "[i]f *any* 'significant' environmental impacts might result from the proposed agency action," then the agency must take the third type of action contemplated under NEPA: "an EIS must be prepared *before* agency action is taken." *Grand Canyon Trust v. Fed. Aviation Admin.*, 290 F.3d 339, 340 (D.C. Cir. 2002) (internal quotation marks and citation omitted).

Complying with NEPA is not a mechanical process. This in part is due to NEPA's vague statutory language. As Justice Marshall said: "[T]his vaguely worded statute seems designed to serve as no more than a catalyst for development of a 'common law' of NEPA." *Kleppe v. Sierra Club*, 427 U.S. 390, 421 (1976) (Marshall, J., concurring in part and dissenting in part). Moreover, even with the interpretive regulations and case law applying NEPA, agencies must make difficult judgments as to how NEPA's mandates apply to the facts at hand—*e.g.*, whether any environmental impacts are "significant" and therefore require an EIS.[2]

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[2] *See* Michael C. Blumm & Stephen R. Brown, *Pluralism and the Environment*, 14 Harv. Envtl. L. Rev. 277, 279 (1990) (explaining NEPA's "process-laden approach to environmental policymaking has both critics and defenders, but both seem to agree that what reviewing courts think NEPA requires of agencies is not predictable"); *see also River Road Alliance v. U.S. Army Corps of Eng'rs*, 764 F.2d 445, 450 (7th Cir. 1985) ("So varied are the federal actions that affect the environment—so varied are the environmental effects of those

NEPA review is lengthy and cumbersome. According to various studies, on average it takes approximately five years to complete an EIS, with many EISs taking well over a decade to complete. One study also estimated that it takes on average 18 months to complete an EA and six months to complete a CE determination.[3]

II. NEPA'S APPLICABILITY

"Federal action[]," the trigger for review under NEPA, is pervasive in our society. 42 U.S.C. § 4332(2)(C). According to Council on Environmental Quality ("CEQ") regulations, "Federal actions" under NEPA are actions "potentially subject to Federal control and responsibility." 40 C.F.R. § 1508.18(b).

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actions—that the decided cases compose a distinctly disordered array . . . .").

[3] *See* Fed. Highway Admin. ("FHWA"), *Evaluating the Performance of Environmental Streamlining: Phase II* § 3.1.1 (2002) (concluding the "NEPATIME median value" was "4.7 years for the 1995-2001 Phase II study period"); FHWA, *Evaluating the Performance of Environmental Streamlining: Development of a NEPA Baseline for Measuring Continuous Performance* § 2.0 (2001) (noting a previous FHWA study concluding that the average time to complete an EIS was approximately five years and that 13% of the projects in the study "took 10 or more years to complete NEPA" and a second study finding that it took 18 months to complete an EA/FONSI and six months to complete a CE); U.S. Gen. Accounting Office, *Agencies Are Attempting to Expedite Environmental Reviews, but Barriers Remain*, at 4 (1994) (discussing study of FHWA projects in which the time required to complete NEPA review ranged from two years to over 12 years); NEPA Task Force, *Report to the Council on Environmental Quality: Modernizing NEPA Implementation*, at 66 (Sept. 2003) ("EISs typically . . . [r]equire from 1 to more than 6 years to complete . . . .").

The regulations list "categories" that "Federal actions" "tend to fall within." *Id.* These categories encompass a wide range of federal activity, ranging from adoption of federal rules and regulations to adoption of treaties and international agreements to "[a]pproval of specific projects, such as construction or management activities," "permit[ting]," and other "federal and federally assisted activities." *Id.* § 1508.18(b)(1)-(4).

As these categories demonstrate, NEPA covers many *types* of federal actions. It also covers a large and growing *number* of federal actions. According to CEQ data, for example, 500 draft and final EISs are prepared annually. Moreover, "approximately 100 EAs are prepared for each EIS," with the estimated number of EAs prepared each year ranging from 30,000-50,000.[4] These numbers do not include the NEPA reviews that conclude with a CE, which historically have not been systematically tracked but which well exceed the number of EAs prepared annually.

The ARRA, moreover, has resulted in many thousands of new federal actions and thus an unprecedented increase in the number of NEPA reviews since the beginning of last year. As of December 31, 2009, there had been over 161,000 NEPA reviews of just stimulus projects, with thousands more still pending. CEQ, *The Fourth*

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[4] *See* CEQ Data, *at* http://ceq.hss.doe.gov/nepa/nepanet.htm ("Number of EISs Filed 1970 to 2007"); Charles H. Eccleston, *Effective Environmental Assessments*, at "Introduction" (2001); *see also* Elisabeth A. Blaug, *Use of the Environmental Assessment by Federal Agencies in NEPA Implementation*, 15 Envtl. Prof. 57, 61 (1993).

Report on the National Environmental Policy Act Status and Progress for American Recovery and Reinvestment Act of 2009 Activities and Projects, at 2 (Feb. 1, 2010).

Although the "actions" subject to NEPA are "Federal," in many cases the actors are *private*. *See, e.g.*, Daniel R. Mandelker, *NEPA Law and Litigation* § 8:19, at 8-46 (2009) (explaining NEPA applies when an agency enables "a nonfederal entity to undertake an activity or a project"). For example, the following are federal actions subject to NEPA that enable important private economic activity: federal permits, such as Clean Water Act § 404 permits needed for development projects[5]; leases or easements on federal land, such as Department of Interior easements needed for construction activity[6]; and federal loans and loan guarantees that enable a wide variety of private initiatives.[7] Under NEPA, these predicate federal actions—as well as the private activity keyed off of these federal actions—must await NEPA review before proceeding. 40 C.F.R. § 1506.1.

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[5] 33 C.F.R. pt. 325, Appendix B.

[6] 73 Fed. Reg. 61,315 (Oct. 15, 2008) (to be codified at 43 C.F.R. pt. 46) (see § 46.30 for definition of "proposed action").

[7] 7 C.F.R. pt. 1794 (Rural Utilities Service financial assistance); 10 C.F.R. § 1021.216 (Department of Energy financial assistance).

III. NEPA LITIGATION

"NEPA does not authorize a judicial review, and its legislative history does not indicate whether judicial enforcement of NEPA was contemplated." Mandelker, *supra*, § 1:5, at 1-9. Nevertheless, courts have held that NEPA's mandates are judicially enforceable. *See, e.g., Scientists' Inst. for Pub. Info., Inc. v. Atomic Energy Comm'n*, 481 F.2d 1079, 1088-89 (D.C. Cir. 1973). As a result, opponents of federal and related private actions regularly use litigation over NEPA's "procedural" mandates to paralyze the actions.

On average, well over 100 NEPA suits are filed each year according to CEQ data covering 2001 to 2008.[8] This is an increase over the 1990s, when less than 100 NEPA suits were filed on average per year. *See* Jay E. Austin et al., *Judging NEPA: A "Hard Look" at Judicial Decision Making Under the National Environmental Policy Act*, Envtl. L. Inst., at 6 (2004). Moreover, with the many thousands of new federal projects and thus additional NEPA reviews conducted pursuant to the federal stimulus program, the number of NEPA lawsuits likely will grow in the near future.

The vast majority of NEPA suits are brought by plaintiffs aiming to halt federal action due to non-compliance with NEPA's "procedural" demands. *See, e.g.*, Austin et al., *supra*, at 8. Moreover, although NEPA suits are styled as against the relevant federal agency, the target of the injunctive relief often is the

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[8] *See* CEQ Data, *at* http://ceq.hss.doe.gov/nepa/nepanet.htm (2001 to 2008 Litigation Surveys).

private activity authorized, funded, or otherwise enabled by the federal action. In other words, the goal of the NEPA suit is to halt—and thereby, as a practical matter, oftentimes kill—private activity that is enabled by federal action.[9]

In part due to NEPA's vague mandates, federal judges have substantial discretion to grant these plaintiffs relief and to find an error under NEPA—even when applying a deferential standard of review. As a leading treatise on NEPA explains, the case law "can provide guidance on legal questions" but "less guidance on mixed factual and legal questions, such as whether an agency action has a significant impact on the quality of the human environment." Mandelker, *supra*, § 8:1, at 8-4.

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[9] *See, e.g., White Tanks Concerned Citizens, Inc. v. Strock*, 563 F.3d 1033 (9th Cir. 2009) (NEPA challenge to issuance of Clean Water Act § 404 permit authorizing housing development); *Ctr. for Biological Diversity v. Kempthorne*, 588 F.3d 701 (9th Cir. 2009) (NEPA challenge to federal regulations authorizing for five-year period the non-lethal "take" of polar bears and Pacific walrus by oil and gas activities in and along the Beaufort Sea); *New Mexico ex rel. Richardson v. Bureau of Land Mgmt.*, 565 F.3d 683 (10th Cir. 2009) (NEPA challenge to BLM decision to open publicly-owned desert grassland to oil and gas exploration and development); *County of Tooele v. U.S. Dep't of Agric.*, No. 99-15332, 2000 U.S. App. LEXIS 413 (9th Cir. Jan. 7, 2000) (unpublished) (NEPA challenge to loan guarantee by the Department of Agriculture to a bank that financed development of a mobile home park); *City of Davis v. Coleman*, 521 F.2d 661 (9th Cir. 1975) (NEPA challenge to highway construction funded by the FHWA); *Fla. Wildlife Fed'n v. U.S. Army Corps of Eng'rs*, 401 F. Supp. 2d 1298 (S.D. Fla. 2005) (NEPA challenge to issuance of § 404 permit authorizing joint development project between county and private research institute).

In fact, according to studies of NEPA cases at the district court level, the success rate of NEPA plaintiffs is approximately 45%. *See* Austin et al., *supra*, at 8 (2001 to 2004 study showing 44% success rate); Paul G. Kent & John A. Pendergrass, *Has NEPA Become a Dead Issue?*, 5 Temp. Envtl. L. & Tech. J. 11, 15 (Summer 1986) (1969 to 1984 study showing 45.7% success rate). The CEQ data referenced above show that, just from 2001 to 2008, the Government lost 333 NEPA cases, which resulted in an injunction or remand.

When the district court perceives a NEPA violation, the court typically orders further environmental review—*e.g.*, preparation of an EIS or supplemental EIS—as a remedy. *See, e.g.*, Pet.App.52a (district court here ordering EIS); *Ilio'Ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1087 (9th Cir. 2006) (requiring Army to prepare supplemental impact statement). The question then becomes the matter at issue here: Should the federal action—and all private activity triggered by that federal action—be further halted pending completion of the further environmental review?

IV. THE DECISIONS BELOW

This case exemplifies the NEPA process, and pitfalls, described above. Six years ago, in 2004, Petitioners asked the U.S. Department of Agriculture's Animal and Plant Health Inspection Service ("APHIS") to deregulate Roundup Ready alfalfa ("RRA") under the Plant Protection Act. 7 U.S.C. § 7701; 7 C.F.R. §§ 340.0(a)(2) n.1, 340.6. In response, APHIS did an environmental study, prepared an EA, and, in June 2005, issued a FONSI.

70 Fed. Reg. 36,917-36,919 (June 27, 2005). Based on its environmental review and applying the statutory standards governing deregulation petitions under the PPA, APHIS also issued a determination in June 2005 deregulating RRA on the grounds that the environmental risks contemplated by the PPA were small. *Id.* "[I]n reliance on the . . . June 2005 deregulation decision," growers, seed distributors, and others made investments in RRA. Pet.App.55a, 64a. Growers also planted significant quantities of RRA without any harm to anyone. *Id.*

Respondents—led by an environmental group opposed to the proliferation of genetically modified products—filed suit in February 2006 alleging in relevant part that APHIS violated NEPA by deregulating RRA without first preparing an EIS. In February 2007, the district court issued an order recognizing that this case presents a "close question of first impression" but nevertheless holding that APHIS violated NEPA. Pet.App.27a. The court found, *inter alia*, that the possibility of cross-pollination of conventional and organic alfalfa with RRA posed "significant" environmental risks requiring preparation of an EIS. Pet.App.52a. Because the court concluded that the agency did not adequately comply with NEPA's procedural mandate, it stated that it did not need to address the underlying substantive agency decision deregulating RRA. *Id.*

After this ruling—and 21 months after APHIS's deregulation order—Respondents for the first time moved for injunctive relief that would prevent all future planting and sales of RRA nationwide. Pet.App.55a, 58a. APHIS countered with a proposed

injunctive order that reflected its substantive analyses and findings and its lengthy experience with genetically modified products, and that quite reasonably balanced the competing interests. Pet.App.161a-67a. Specifically, the proposed injunction would have allowed planting of RRA but only pursuant to stewardship measures to even further diminish any risk of cross-pollination pending completion of the EIS. APHIS explained that, based on its "many years of experience" and analysis of relevant scientific studies, these stewardship measures would reduce the risk of cross-pollination to virtually zero. Pet.App.137a-57a.

The district court, however, refused to credit APHIS's technical expertise or scientific findings, to hold an evidentiary hearing, or even to consider the critical evidence on irreparable harm. In the court's view, this is what "APHIS . . . must do in an EIS"—it "isn't my job." Pet.App.68a-69a, 417a. Having refused to engage on the question of likely irreparable harm, the court rejected out of hand APHIS's proposal. Pet.App.67a. Instead, the court entered an injunction prohibiting all future planting of RRA nationwide pending completion of the EIS. Pet.App.79a.[10]

The Ninth Circuit affirmed. The majority specifically agreed that the district court did not need to "resolve the very disputes over the risk of environmental harm that APHIS would have to

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[10] The Court entered a preliminary injunction in March 2007 (Pet.App.54a-59a) and a permanent injunction in April 2007 (Pet.App.60a-79a). The injunction prohibits all planting of RRA from March 30, 2007 through completion of an EIS. Pet.App. 79a.

consider in the EIS" and thus "duplicate the [agency's] efforts." Pet.App.19a-20a, 95a-96a. The majority also held that the district court was justified in ignoring APHIS's experience, analyses, and findings relevant to its substantive decision to deregulate, as well as its remedial proposal. Pet.App.15a-16a, 93a-94a. The Ninth Circuit thus sanctioned the district court's own nationwide injunction that halts APHIS's deregulation decision—and important economic activity keyed off of that decision—throughout the entire country to this very day.

ARGUMENT

I. THIS COURT SHOULD REAFFIRM THAT LIKELY IRREPARABLE HARM IS A PREREQUISITE TO INJUNCTIVE RELIEF

An injunction is an "extraordinary remedy" that does not issue "as of course." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-12 (1982). Thus, according to "well-established principles of equity," a plaintiff must show four factors before a permanent injunction will issue: (1) he is "likely to suffer irreparable harm," (2) "remedies available at law, such as monetary damages, are inadequate to compensate for that injury," (3) "the balance of equities tips in his favor," and (4) "an injunction is in the public interest." *Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 374 (2008); *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

Although this Court repeatedly has applied this four-part test, and never has suggested that its

elements can be relaxed, courts continue to grant injunctions without a threshold finding of likely irreparable harm. For example, in this case, the courts below held that, because the irreparable harm inquiry overlapped with the agency's further environmental review, it was not the district court's "job" to determine irreparable harm because the agency could once again address issues related to environmental risk on remand. Thus, as described *infra*, the lower courts effectively carved out a subject-matter exception that alleviates the need to show irreparable harm in NEPA cases.

Moreover, in the context of preliminary injunctions—where the plaintiff must additionally show a likelihood of success on the merits—some courts relax the likely irreparable harm requirement through use of the so-called "sliding scale" standard.[11] Under this standard, a strong showing of likelihood of success on the merits alleviates the need to show a likelihood of irreparable harm (and vice versa). *See, e.g., Vaqueria Tres Monjitas, Inc. v. Irizarry*, 587 F.3d 464, 485 (1st Cir. 2009) (explaining "the measure of irreparable harm is not a rigid one; it has been referred to as a sliding scale, working in conjunction with a moving party's likelihood of success on the merits"). Specifically, the First Circuit and Federal Circuit continue to use the sliding scale standard. *See id.*; *Qingdao Taifa Group Co., Ltd. v. United States*, 581 F.3d 1375, 1378-79

[11] "The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits." *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 546 n.12 (1987).

(Fed. Cir. 2009). The D.C. Circuit has recognized its tension with *Winter* but reserved judgment on its validity. *See Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009). The Ninth Circuit has cases both applying and rejecting the standard in light of *Winter*.[12]

But any approach that eliminates the need to show likely irreparable harm as a prerequisite to injunctive relief cannot be squared with this Court's cases. This Court consistently has stated that each equitable factor—including likely irreparable harm—must be met before injunctive relief is appropriate. *See supra* at 16. In fact, contrary to the lower court decisions in this case, the Court has required a showing of likely irreparable harm even in the face of ongoing agency review. *See, e.g.*, *Winter*, 129 S. Ct. at 376, 381 & n.5 (Navy conducting ongoing EIS); *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 538-39 (1987) (noting the Secretary's "postsale" evaluation); *Weinberger*, 456 U.S. at 315 n.9 (Navy application for permit under consideration by the Environmental Protection Agency). And, contrary to

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[12] *Compare Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1052 (9th Cir. 2009) (stating that, after *Winter*, a court has to find likelihood of irreparable injury); *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009) (same); *Fisher Sand & Gravel Co. v. Clark County*, No. 2:09-cv-01372-RCJ-GWF, 2010 WL 99218, *4 (D. Nev. Jan. 6, 2010) (same; explicitly stating the sliding scale approach is invalid after *Winter*), *with Greater Yellowstone Coal. v. Timchak*, 323 Fed. Appx. 512, 514 n.1 (9th Cir. 2009) (unpublished) (explaining *Winter* "did not reject the sliding scale approach we employ in the alternative"); *Veterans for Peace Greater Seattle, Chapter 92 v. City of Seattle*, No. C09-1032-RSM, 2009 WL 2243796, at *3 (W.D. Wash. July 24, 2009) (same).

the decisions applying the sliding scale approach, the Court has required a showing of likely irreparable harm regardless of the likelihood of success on the merits. *See, e.g., Winter*, 129 S. Ct. at 381 n.5 ("[W]e find the injunctive relief granted in this case an abuse of discretion, even if plaintiffs are correct on the underlying merits.").

Just within the last two Terms, the Court has *emphasized* the importance of finding each element of the equitable test and specifically the threshold element of likely irreparable harm. Last Term, *Winter* specifically rejected that injunctive relief can be granted without a showing of likely (as opposed to possible) irreparable harm. *Id.* at 375-76. As the Court explained, "[i]ssuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.*

More recently, in *Nken v. Holder*, 129 S. Ct. 1749 (2009), the Court addressed the related standard for a stay and emphasized that the "first two factors"—strong likelihood of success and likelihood of irreparable harm—"are the most critical." *Id.* at 1761. Only after "an applicant satisfies [these] factors," the Court held, does "the traditional stay inquiry call[] for assessing the harm to the opposing party and weighing the public interest." *Id.* at 1762. Justice Kennedy was even more pointed in his concurrence: "When considering success on the merits and irreparable harm, courts cannot dispense with the required showing of one simply because there is a strong likelihood of the other." *Id.* at 1763;

see also Munaf v. Geren, 128 S. Ct. 2207, 2219 (2008) (explaining the "basics," including that "[a] preliminary injunction is an extraordinary and drastic remedy; it is never awarded as of right. Rather, a party seeking a preliminary injunction must demonstrate, among other things, a likelihood of success on the merits.").

These cases are based on equity's recognition that granting injunctive relief is "an exercise of a very far-reaching power, never to be indulged in except in a case clearly demanding it." *Warner Bros. Pictures, Inc. v. Gittone*, 110 F.2d 292, 293 (3d Cir. 1940) (per curiam). Without the likelihood of irreparable harm, the exercise of this far-reaching power simply is not justified. In this case, this Court should make clear once and for all that, without exception, an injunction can only issue where there is a likelihood of irreparable harm.

II. THE THRESHOLD REQUIREMENT OF LIKELY IRREPARABLE HARM PLAYS A CRITICAL ROLE IN NEPA CASES

Instead of requiring a likelihood of irreparable harm as a prerequisite to injunctive relief, the courts below effectively carved out a NEPA-based exception: Whenever a court orders further environmental review to cure a statutory or regulatory violation, then it is not the court's "job" to engage on the question of likely irreparable harm because that question will later be addressed by the agency. Regardless of what the agency had said, the lower courts reasoned, the question of likely irreparable harm could be addressed (again) by the agency.

This Court, however, has rejected that environmental cases—or any other types of cases—are exempted from equity's stringent limitations on injunctive relief. *See, e.g., Winter*, 129 S. Ct. at 374-75; *Weinberger*, 456 U.S. at 311 (rejecting "absolute statutory obligation" to enjoin violations of environmental statutes (internal quotation marks and citation omitted)); *Amoco Prod. Co.*, 480 U.S. at 542-45 (rejecting presumption of irreparable harm in environmental cases); *see also eBay*, 547 U.S. at 391-94 (rejecting automatic injunction following patent violation).

Nor should the Court adopt an exception in this case. The likely irreparable harm requirement serves a critical role in NEPA cases. Specifically, it ensures that the substantial costs imposed by further delay of federal and private action is warranted by the countervailing justification that only through such delay can likely irreparable harm be prevented. Without that countervailing justification, imposing these costs on the federal agency and private actors depending on the agency action is inequitable.

The costs imposed by an injunction in a NEPA case are well demonstrated here. Petitioners submitted their petition to deregulate RRA under the PPA in 2004, approximately six years ago. In June 2005, almost five years ago, APHIS found that the petition met the requirements for deregulation. In early 2007, however, and without ever having reached the merits of the final decision to deregulate, the district court here issued a nationwide injunction halting the deregulation decision and preventing any further growing of RRA. Today—almost five years after APHIS determined that the statutory

standards for deregulating RRA were satisfied, and three years after the district court entered its injunction—the deregulation of RRA is still delayed nationwide while the agency complies with NEPA's "procedural" command.

The monetary costs of this delay are enormous. One agricultural economist estimated that the cost of Respondents' proposed nationwide injunctive relief would cause growers who had planted or would plant RRA to lose more than $200 million in the first two years of the injunction and that seeds companies, distributors, and dealers would lose approximately $20 million. Pet.App.267a-69a. A Monsanto officer estimated that Monsanto would lose approximately $27 million in revenue from technology premiums as well. J.A.584-85.

There also are many costs that cannot be reduced to monetary terms. For example, trading partners that have approved RRA, and that seek to import that product from the U.S., will be deprived of a major source of RRA as a result of the injunction halting the deregulation decision. Pet.App.146a (noting Japan approves RRA and that 75% of the alfalfa exported from the U.S. in 2006 went to Japan). Moreover, as an APHIS official observed, "[t]he uncertainty of the status of RRA will likely create general confusion and a lack of confidence among trading partners regarding past and future determinations of nonregulated status of [genetically engineered] plants by" the agency, which could cause trading partners to reconsider accepting genetically engineered plants from the U.S. or impose expensive testing requirements. Pet.App.146a-47a.

This case, moreover, is just one of dozens of NEPA cases that the Government loses each year, each of which will present the question of whether it is equitable to stall federal and private action—and thus impose enormous costs like those described above—pending further and potentially lengthy environmental review. In some cases, injunctive relief will impose costs even higher than those described above—including effectively ending the federal and private action. As one court said regarding the type of further environmental review ordered here, preparation of an EIS "is very costly and time-consuming . . . and has been the kiss of death to many a federal project." *City of Dallas v. Hall*, 562 F.3d 712, 717 (5th Cir. 2009) (internal quotation marks and citation omitted).

This issue will become even more stark in light of the Government's stimulus effort. The whole point of the stimulus is to create jobs quickly and to inject money into the economy by immediately starting "shovel ready" projects. Yet these projects have to go through NEPA review and, after that review, plaintiffs will file NEPA suits seeking to delay some of these projects.[13] Courts should not halt these stimulus projects—and thus defeat their very purpose—unless a plaintiff can show, in addition to convincing one judge of a technical error under

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[13] *See* Steven Jones, *What's Ahead? The Year Ahead in Energy and Environmental Law* (Jan. 14, 2010), *available at* http://www.martenlaw.com/news/?20100114-environmental-review-2010 (noting that "dozens" of stimulus projects have been "tied up in litigation" and that "[w]e anticipate many more stimulus projects to be subject to challenge in 2010 as project opponents gain familiarity with using climate change as a basis to force more environmental review and alternatives analysis").

NEPA, that extraordinary injunctive relief is necessary to prevent likely irreparable harm to the environment.

Finally, the implications of the rationale employed below extend beyond NEPA cases. Courts routinely order further environmental review to cure violations of various environmental statutes. *See, e.g., Amoco Prod. Co.*, 480 U.S. at 544 (reversing preliminary injunction in case where Ninth Circuit ordered further review to comply with the Alaska National Interest Lands Conservation Act, which in relevant part requires "a procedure" through which actions that "would adversely affect subsistence resources" must be considered and undertaken only if "they are necessary and if the adverse effects are minimized"). As Judge Smith said in his dissent, "[t]here aren't many environmental cases that don't fit into the majority's newly-created exception." Pet.App.26a, 102a-03a.

This Court has cautioned against courts using NEPA to "unjustifiably intrud[e] into the administrative process." *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519, 556 (1978). By sanctioning nationwide injunctive relief without a finding of likely irreparable harm, the Ninth Circuit endorsed just such an unwarranted intrusion here.

III. THE INJUNCTION STANDARD ADOPTED BELOW LEAVES TOO MUCH ROOM FOR JUDICIAL ACTIVISM AND NO ROOM FOR AGENCY DEFERENCE

The rationale of the decisions below—that a court need not engage on irreparable harm when further environmental review is to come—also upsets the proper relationship between the courts and agencies. Specifically, eliminating the need to find likely irreparable harm before issuing an injunction (1) removes a critical check on judicial overreaching under the auspices of NEPA, and (2) forecloses deference to any agency's expert conclusion that measures short of a broad injunction are sufficient to mitigate any risk of harm during further environmental review.

Allowing courts to grant injunctive relief in NEPA cases against federal or private action without finding irreparable harm places immense and unconstrained power in the hands of federal judges. This is especially true given the nature of the NEPA merits inquiry. NEPA's standards are vague and, as a consequence, judicial review under NEPA is pliable.[14]

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[14] *See* Austin et al., *supra*, at 8-9 (study finding federal district court judges appointed by a Democratic president ruled in favor of environmental plaintiffs just under 60% of the time, while judges appointed by a Republican president ruled in their favor approximately 28% of the time and even more "striking patterns" in the three-judge panels of federal circuit courts); *see also* Jamison E. Colburn, *The Indignity of Federal Wildlife Habitat Law*, 57 Ala. L. Rev. 417, 488 n.280 (2005) (noting NEPA has "tended to be especially sensitive to shifts within the judiciary and, in particular, the composition of courts hearing NEPA cases"); Blumm & Brown, *supra*, at 280 (arguing the

Thus, by affirming that it is not a district court's "job" to determine irreparable harm in NEPA cases before granting an injunction, the Ninth Circuit has removed a critical check on the exercise of judicial power under NEPA. Without the irreparable harm requirement, a NEPA case is transformed into a right to veto—at least for a substantial period, if not forever—federal projects with which the judge may politically disagree.

At the same time, the standard adopted below leaves no room for deference to the agency on the appropriate remedy in a NEPA case. Specifically, by holding that a district court's "job" does not include weighing the question of harm before issuing injunctive relief, the decision below renders the agency's view as to whether there will be any environmental harm without an injunction—or whether lesser measures than broad injunctive relief will prevent any harm—irrelevant.

"notion that NEPA cases may be a function of judicial whim is unfortunate for several reasons"); Christopher Cumings, Comment, *Judicial Iron Triangles: The Roadless Rule to Nowhere—And What Can Be Done to Free the Forest Service's Rulemaking Process*, 61 Okla. L. Rev. 801, 815 (2008) (surveying the NEPA "roadless rule" cases and explaining "the most common and accurate indicator of how a judge would rule in" these cases "was the political party of the president who nominated him or her"); Jeannette MacMillan, Note, *An International Dispute Reveals Weaknesses in Domestic Environmental Law: NAFTA, NEPA, and the Case of Mexican Trucks (Department of Transportation v. Public Citizen)*, 32 Ecology L.Q. 491, 523 (2005) ("NEPA's pliability makes it particularly susceptible to reflecting a judge's ideology.").

Deference to an agency's views on the risk of irreparable harm—and how any harm can be mitigated short of a broad injunction—is particularly appropriate in a case where the agency has scientific expertise and extensive experience that it can bring to bear. *See, e.g., Utah Envtl. Congress v. Bosworth*, 443 F.3d 732, 739 (10th Cir. 2006) ("Deference to the agency is especially strong where the challenged decisions involve technical or scientific matters within the agency's area of expertise."); *see also EarthLink, Inc. v. FCC*, 462 F.3d 1, 12 (D.C. Cir. 2006) (explaining the court should be "particularly deferential" to an "agency's predictive judgments about areas that are within the agency's field of discretion and expertise . . . as long as they are reasonable").

Here, for example, APHIS and two other agencies—the Environmental Protection Agency and Food and Drug Administration—have been in charge of the evaluation and deregulation of genetically modified crops for more than 15 years. 51 Fed. Reg. 23,302, 23,302-09 (June 26, 1986); *see also* Pet.App.195a-202a (discussing role of EPA); Attachment to EA/FONSI, Response to Comments, APHIS No. 04-110-01, at 4 ("FDA has completed their consultation and had no further questions about the food or feed safety of alfalfa derived from events J101 or J163"). Prior to granting the present deregulation petition, APHIS had granted 66 other petitions to deregulate a genetically engineered crop. Ten of these concerned a glyphosate-resistant crop like RRA, including corn, cotton, soy, canola, and

sugarbeets.[15] With respect to RRA, APHIS authorized the field testing of RRA in 1998, "and has authorized a total of 297 such field trials over a period of approximately eight years." Pet.App.140a.

APHIS also is well-versed on the issue of cross-pollination. Putting aside APHIS's experience with respect to other genetically engineered crops, APHIS specifically addressed cross-pollination with respect to RRA in response to comments in the EA/FONSI and in the interim period after the district court ordered further environmental review but before the court entered its final order on the appropriate remedy. *See* Attachment to EA/FONSI, Response to Comments, APHIS No. 04-110-01, at 2; Pet.App.158a-67a (APHIS official's declaration discussing proposed stewardship measures with reference to relevant studies); *see also* Appendix D to EA/FONSI, Determination of Non-regulated Status for Round-up Ready Alfalfa Events J101 and J163 (June 14, 2005) (determining "gene introgression" is "extremely unlikely").

Based on its expertise and experience, APHIS not only decided to deregulate RRA (a decision the courts never reached), but after the finding of a NEPA error, it proposed more tailored injunctive relief that included stewardship measures to ensure that any risk of harm from cross-pollination pending completion of the EIS would be virtually zero. Pet.App.161a-67a. But instead of giving any deference to the expert agency and its scientific

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[15] *See* APHIS, EPA, *Petitions of Non-Regulated Status Granted or Pending by APHIS as of February 2, 2010*, at http://www.aphis.usda.gov/brs/not_reg.html; Pet.App.140a.

findings, the district court gave APHIS's view no weight at all.[16] Pet.App.67a. The Ninth Circuit then compounded that error by deferring *to the district court* and not APHIS. Pet.App.26a, 102a (Smith, J., dissenting) ("Instead of giving deference to the agency's expertise, the majority gives deference to the district court, despite its wholesale rejection of the agency's proposal for an injunction and its failure to hold an evidentiary hearing."). The result is that, throughout the entire country, planting of RRA remains prohibited—even in places where there is literally no risk of cross-pollination at all. This absurd result should be corrected.

Finally, in addition to foreclosing deference to the expert agency, the Ninth Circuit's decision will result in private entities whose interests are critically affected by a NEPA suit being foreclosed from meaningful participation in that suit. As previously described, although NEPA actions are styled as against the federal agency, it is the private actors and action that NEPA suits often aim to halt. Thus, private actors have important interests—sometimes the viability of their businesses—at stake in NEPA litigation.

Nevertheless, the Ninth Circuit categorically prohibits mandatory intervention under Federal Rule of Civil Procedure 24(a) by private actors at the

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[16] Of course, had the court reached APHIS's decision to deregulate, it would have had to defer to that agency's findings. *See, e.g., Cactus Corner, LLC v. U.S. Dep't of Agric.*, 450 F.3d 428, 433 (9th Cir. 2006). That the court disposed of this case based on a technical NEPA violation without reaching the decision to deregulate does not mean that APHIS's views are entitled to any less weight.

merits stage of a NEPA suit. *See, e.g., Wetlands Action Network v. U.S. Army Corps of Eng'rs*, 222 F.3d 1105, 1114 (9th Cir. 2000). The Ninth Circuit reasons that only the relevant federal agency can comply with NEPA and therefore only that agency can defend compliance with NEPA on the merits. *Id.*

Moreover, courts generally deny private actors *permissive* intervention under Rule 24(b) at the merits stage of NEPA actions as well. For example, in an ongoing NEPA and PPA challenge to deregulation of Roundup Ready sugarbeets, the district court recently denied permissive intervention at the merits stage to owners of the intellectual property related to Roundup Ready sugarbeets, growers of sugarbeets, and others with important private interests in the outcome of the suit. *See Ctr. for Food Safety v. Connor*, No. C 08-00484 JSW, 2008 U.S. Dist. Lexis 65867 (N.D. Cal. Aug. 15, 2008). The court reasoned that "no common issues of law or fact exist during the merits phase of this action because the only issue in this phase is whether the federal government complied with NEPA and the PPA." *Id.* at *9-*10; *see also W. Watersheds Projects v. U.S. Forest Serv.*, No. C 08-1460 PJH, 2008 WL 2952837, at *6-*7 (N.D. Cal. July 30, 2008) (denying permissive intervention in NEPA suit). Under this reasoning, permissive intervention by private actors is effectively barred at the merits stage of a NEPA suit.

The courts do allow intervention by private actors at the *remedies* stage of NEPA litigation. *See, e.g., Wetlands Action Network*, 222 F.3d at 1114; *Ctr. for Food Safety*, 2008 U.S. Dist. Lexis 65867, at *10. But participation at the remedies stage is futile if, as

the courts below effectively held, injunctive relief flows from the mere fact of a NEPA violation. Thus, the net effect of limiting intervention to the remedies stage and making injunctive relief flow from the mere fact of a NEPA violation is that many private entities will be denied *any* due process related to NEPA suits that affect their interests.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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March 8, 2010

AMICUS CURIAE BRIEF

No. 09-475

In The
Supreme Court of the United States

MONSANTO COMPANY, et al.,

Petitioners,

v.

GEERTSON SEED FARMS, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF *AMICI CURIAE* CROPP COOPERATIVE; MONTANA ORGANIC ASSOCIATION; NATIONAL COOPERATIVE GROCERS' ASSOCIATION; NATIONAL ORGANIC COALITION; ORGANIC FARMING RESEARCH FOUNDATION; ORGANIC SEED ALLIANCE; ORGANIC SEED GROWERS AND TRADE ASSOCIATION; ORGANIC TRADE ASSOCIATION; WESTERN ORGANIC DAIRY PRODUCERS ALLIANCE; UNITED NATURAL FOODS, INC.; ANNIE'S, INC.; CLIF BAR & COMPANY; EDEN FOODS, INC.; NATURE'S PATH FOODS, INC.; PURIST FOODS, INC.; STONYFIELD FARM, INC.; AND STRAUS FAMILY CREAMERY IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI CURIAE*

Amici are commercial and public interest members of the organic community, as either growers of organic grains, fruits, or vegetables; organic livestock owners; sellers of organic products; or organizations dedicated to the integrity of the organic label.[1] As stakeholders whose livelihood or interests will be harmed by the release of Petitioner Monsanto's genetically engineered ("GE") alfalfa into the environment, *amici* have a strong interest in presenting their concerns regarding the unrestricted use of product lines J101 and J163 (collectively, Roundup® Ready Alfalfa or "RRA"), especially regarding their own or their members' ability to choose to produce or sell organic products. Thus, *amici* urge the Court to uphold the decision of the Ninth Circuit prohibiting the planting of RRA until the government has completed its Environmental Impact Statement ("EIS") and the U.S. Department of Agriculture ("USDA") has issued a new decision on whether to deregulate RRA based on the EIS.

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[1] All parties have consented to the filing of this brief, and the consent letters are on file with the Clerk in accordance with Supreme Court Rule 37.2(a). No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici*, their institutions, or their counsel made a monetary contribution to its preparation or submission.

Amicus CROPP Cooperative is the nation's largest farmer-owned cooperative, with over 1,600 organic farmers located in 30 states. CROPP Cooperative's members include certified organic dairy farmers, beef and pork producers, and feed crop growers, all of which rely on the availability of certified organic alfalfa. CROPP Cooperative markets certified organic products under the brands Organic Valley Family of Farms® and Organic Prairie Family of Farms®. CROPP Cooperative's members face a significant decline in the marketability of organic products and a significant increase in production costs should RRA contaminate organic alfalfa crops.

Amicus Montana Organic Association ("MOA") is a nonprofit organization that provides education, information, and assistance to organic producers, processors, and related parties. MOA's members depend on ample supplies of certified organic alfalfa, and wish to grow crops and livestock feed without the threat of contamination by RRA.

Amicus National Cooperative Grocers' Association ("NCGA") is a business services cooperative that helps unify co-ops to optimize operational and marketing resources, strengthen purchasing power, and offer more value to natural food co-op shoppers. It comprises 114 food co-ops nationwide, with members operating more than 145 stores in 32 states with combined annual sales of nearly $1.2 billion. NCGA supports consumers' right to have access to organic foods free from GE contamination, and believes that RRA stands not only

to compromise that right but also the integrity of the organic label.

Amicus National Organic Coalition ("NOC") is a national alliance of farmer and rancher associations, environmentalists, consumer and food safety groups, and progressive industry members involved in organic agriculture and in upholding the integrity of the organic label. NOC believes the integrity of the organic label and the ability of its members to meet consumer expectations and foster organic markets are dependent upon the exclusion of GE products, ingredients, and methods from organic products.

Amicus Organic Farming Research Foundation ("OFRF") is a national charitable foundation dedicated to the widespread adoption and improvement of organic farming systems. OFRF's policy objectives are to ensure that the public and policymakers are well informed about organic farming issues and to increase public institutional support for organic farming research and education. OFRF supports organic farmers' rights to grow and sell their products without the threat of contamination by GE products. By charter, the majority of OFRF's Directors are certified organic producers.

Amicus Organic Seed Alliance ("OSA") is a non-profit organization with a mission to support the ethical development and stewardship of seed. OSA accomplishes its goals through advocacy, education, and research with organic farmers and other agricultural professionals.

Amicus Organic Seed Growers and Trade Association ("OSGATA") is the trade association for organic seed farmers, breeders, companies, and supporters. OSGATA develops, protects and promotes the organic seed trade and its growers, and strives to ensure that the organic community has access to high quality organic seed. OSGATA believes that organic seed is the foundation of organic crop agriculture and that the integrity of the organic industry rests upon the availability of organic seed free from GE product contamination.

Amicus Organic Trade Association ("OTA") is the membership-based business association for the organic industry in North America focused on issues impacting organic agriculture and its products. OTA believes that organic stakeholders' livelihoods will be harmed by the release of GE alfalfa into the environment.

Amicus Western Organic Dairy Producers Alliance ("WODPA") is a membership organization whose mission is to preserve, protect, and ensure the sustainability and integrity of organic dairy farming across the West. WODPA believes that GE contamination of alfalfa will severely curtail the availability of organic hay used as forage to feed organic dairy cows, and will result in catastrophic impacts on the organic dairy industry and WODPA's member farmers.

Amicus United Natural Foods, Inc. ("UNFI") is the nation's leading distributor of natural, certified organic, and specialty foods with sales of nearly $4 billion annually in the United States. UNFI operates

20 distribution centers serving 17,000 retail locations, and fears that its ability to meet market demand for products reliably free of GE organisms is at risk from the introduction of RRA.

Amicus Annie's, Inc. produces natural and certified organic food under two brands, Annie's Homegrown and Annie's Naturals. Annie's is concerned that customer expectation for certified organic foods to be completely free of genetically modified ingredients will be eroded by the introduction of RRA, threatening its business.

Amicus Clif Bar & Company is the leading maker of organic, natural energy bars and healthy snacks in North America. Clif Bar & Company is committed to protecting the integrity of the organic supply chain, from the farmer to the consumer, and its business depends on the availability of certified organic products.

Amicus Eden Foods, Inc. is the oldest natural foods company in the United States and the largest independent manufacturer of dry grocery organic foods. To satisfy customer demands, Eden Foods has been burdened with the enormous and costly responsibility of avoiding genetically modified organisms. Eden Foods believes the introduction of RRA will only increase this burden.

Amicus Nature's Path Foods, Inc. is North America's largest certified organic breakfast cereal manufacturer. Nature's Path is affected by organic consumer opinion, and believes consumer demand for its products will be impacted should organic alfalfa become contaminated by RRA.

Amicus Purist Foods, Inc. produces natural and certified organic food under the brand name White Mountain Foods. Purist Foods relies on certified organic milk to produce its line of organic yogurt, and fears that widespread introduction of RRA will lead to a significant decrease in the availability of certified organic milk as organic alfalfa supplies become contaminated.

Amicus Stonyfield Farm, Inc. is the largest organic yogurt manufacturer in the world, and the third largest yogurt brand in the U.S. Stonyfield Farm purchases certified organic milk from the member farmers of *amicus* CROPP Cooperative, and fears that the economic viability of its business will be in peril if supplies of organic alfalfa become contaminated by RRA.

Amicus Straus Family Creamery produces delicious, high quality certified organic dairy products from the Straus family dairy and two other organic dairy farms in California. Straus Family Creamery relies on organic alfalfa for feed, and is concerned that introduction of RRA will lead to widespread contamination of organic alfalfa supplies and weaken the integrity of the organic label.

SUMMARY OF ARGUMENT

Petitioner Monsanto Company ("Petitioner") wishes to sell a product unregulated in the market place, without concern that the product will, by Petitioner's own acknowledgement, contaminate the

products of a successful, $25 billion industry. Petitioner desires this Court overturn the careful, cautious decision of the lower courts requiring the USDA to take a hard look at this question of contamination before allowing the unregulated sale of Petitioner's product. The role of the courts is to assure that government agencies avoid decisions which unintentionally harm existing stakeholders. In this case, the lower courts clearly found that the agency had not undertaken the requisite review, and that without that review, it would be irresponsible to allow the unregulated sale of Petitioner's products.

Petitioner's dual lines of RRA were developed by inserting a gene into an alfalfa plant. This gene was developed in a laboratory, and it makes the final product lines resistant to another one of Petitioner's products, a glyphosate herbicide marketed as Round-up®. Conventional alfalfa has no natural resistance to Roundup, but RRA can survive the herbicide application which is then used to kill all surrounding weeds.

This case raises important issues of the ability of courts to prevent irreparable harm to commercial stakeholders, such as *amici*, through the issuance of injunctive relief. In this case, Respondents Geertson Seed Farms and Trask Family Seeds, along with a number of environmental groups, filed suit in district court challenging the USDA's decision to deregulate Petitioner's RRA without issuing the requisite EIS under National Environmental Policy Act ("NEPA") for "major Federal actions significantly affecting

the quality of the human environment." 42 U.S.C. § 4332(2)(C). Based on an extensive review of the record, the district court concluded that the USDA, acting through the Animal and Plant Health Inspection Service ("APHIS") violated NEPA by failing to take the necessary "hard look" at the significant environmental consequences of deregulating RRA. As the district court correctly recognized, APHIS inadequately explained why cross-pollination of conventional and organic alfalfa by RRA would not create a significantly harmful impact on the environment. Pet.App. 38a. In particular, the district court pointed towards a number of decisional inadequacies: APHIS "made no inquiry into whether those farmers who do not want to grow genetically engineered alfalfa can, in fact, protect their crops from contamination, especially given the high geographic concentration of seed farms and the fact that alfalfa is pollinated by bees that can travel more than two miles," Pet.App. 38a; APHIS failed to consider whether, for climate-related reasons, organic farmers might be forced to harvest forage alfalfa during a time when alfalfa seed might be subject to cross-contamination, Pet.App. 39a; and APHIS failed to adequately consider the effects on organic farmers' ability to continue to exercise their choice in marketing organic products. Pet.App. 40a.

The district court then issued a permanent injunction order, again evaluating the extensive record and ultimately concluding that "plaintiffs have sufficiently established irreparable injury and that the balance of the equities weighs in favor of

maintenance of the status quo and against allowing the continued expansion of the RRA market pending the government's completion of the EIS." Pet.App. 60a-79a. In reaching this conclusion, the district court recognized that contamination of organic crops by RRA has already occurred, and that this contamination "cannot be undone; it will destroy the crops of those farmers who do not sell genetically engineered alfalfa." Pet.App. 71a. Moreover, the district court balanced the equities to all potential stakeholders, comparing the loss of anticipated revenue to Monsanto and farmers who desire to plant RRA against the harm faced by organic growers, Pet.App. 72a, and rejecting the argument that the use of RRA would promote the use of less-toxic herbicides, given the fact that most conventional forage alfalfa is grown without the use of any herbicides. Pet.App. 74a-75a.

The district's court's order was carefully tailored. It avoided expanding its injunction to encompass either RRA already planted in reliance on APHIS's deregulation decision, or even the harvesting and sale of already planted RRA seed, Pet.App. 76a, but instead limited its injunctive relief to future plantings of RRA – that is, a "maintenance of the status quo." Pet.App. 64a. Again, this decision was based on a comprehensive balancing of the equities involved in this case, considering the "drastic" nature of completely prohibiting the use of previously planted RRA. Pet.App. 76a.

The Ninth Circuit upheld this permanent injunction, recognizing the extensive review that the

district court already applied. Pet.App. 87a-88a. The Ninth Circuit observed that the district court engaged in the "traditional balance of harms analysis," Pet.App. 91a, and recognized that a NEPA violation alone was insufficient to establish irreparable harm. Moreover, the Ninth Circuit pointed out that the district court had found that existing instances of genetic contamination[2] demonstrated that some injunctive relief was warranted, "though narrower than the blanket injunction sought by the plaintiffs," Pet.App. 91a, and that the district court comprehensively balanced the hardships to Monsanto and GE growers against the harm faced by organic growers, consumers, and members of the public interested in a reasoned study of the impact of the deregulated use of RRA. Pet.App. 92a.

The Ninth Circuit's decision should be upheld.

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[2] As the Ninth Circuit observed, the plaintiffs presented "declarations from seed growers whose crops had been contaminated with the Roundup Ready gene and scientists who opined that genetic contamination is likely to occur." Pet.App. 88a.

ARGUMENT

I. THE ORGANIC FOODS INDUSTRY FACES CATASTROPHIC MARKET COLLAPSE FROM THE SPREAD OF GENETICALLY ENGINEERED ALFALFA.

Since the dawn of agriculture – save for the last fourteen years – mankind has grown a variety of conventional crops with remarkable success without the use of transgenic organisms. Until the widespread introduction of synthetic fertilizers, herbicides and pesticides in the mid-twentieth century, all agriculture was in a sense "organic" because it relied upon natural biological processes for the successful propagation of crops for food. In this way, agriculture sustained human life for millennia before the introduction of genetically modified seed varieties such as RR alfalfa. The "relatively young . . . agricultural biotechnology industry," Brief of *Amici* American Farm Bureau, et al., at 21, represents a recent departure from the methods of crop production that farmers, retailers, and consumers have long successfully expected.

Today, markets and consumers clearly differentiate between "organic" and "conventional" products, and organic products comprise one of the fastest growing market segments in agriculture. JA 407, 823-25. Overall annual sales of certified organic products have approached $25 billion in recent years, and the growth rate for organic foods remained in the double digits for the eleventh straight year in 2008. Organic Trade Association, 2009 Organic Industry Survey 2,

available at http://www.ota.com/pics/documents/01a_OTAExecutiveSummary.pdf. A stroll down the aisles of even the most widely recognized supermarkets reveals that certified organic foods have evolved from a small niche market to a mainstream, economically significant industry. Farmers, food processors, and retailers receive a price premium for certified organic products; alfalfa growers, for example can reap a 40% to 50% premium for certified organic alfalfa, up to $200 per acre. JA 139, 988. CROPP Cooperative members receive similar premiums for certified organic milk. JA 646-47.

Organic dairy farming is central to this national growth, as consumer demand has driven a steady increase in production. Nationwide, the number of certified organic cows grew by an annual average of 25 percent between 2000 and 2005. The organic dairy industry has surpassed $1 billion in annual sales for the past several years, and the sale of organic milk alone was $750 million in 2007. U.S. Department of Agriculture, National Agricultural Statistics Service, *Organic Production Survey* 175 (2008), *available at* http://www.agcensus.usda.gov/Publications/2007/Online_Highlights/Organics/ORGANICS.pdf. *Amicus* CROPP Cooperative, which sells certified organic milk under the brand name Organic Valley® and to third parties, saw certified organic milk sales reach $333 million in 2007. JA 646.

Consumers choose organic products in large part due to the decreased environmental impact of organic production. *See, e.g.*, Organic Trade Association, Consumer Profile Facts, http://www.ota.com/organic/mt/

consumer.html. Organic agriculture results in decreased off-farm inputs; reduced use of pesticides; and increased biodiversity through a holistic production management system. Indeed, the very definition of organic production is a system that integrates "cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity." 7 C.F.R. § 205.2. These ecological benefits lie at the core of the organics industry and drive consumer choices.

The continuing viability of this billion dollar industry depends in large part upon the availability of certified organic alfalfa. Much of the alfalfa hay grown in the U.S. is consumed on dairy farms, with approximately 200,000 total acres of organic alfalfa hay harvested annually. JA 118, 243, 347. Alfalfa is essential for dairy operations; it provides the highest quality forage available, rich in protein, fiber, and energy. JA 652, 988. CROPP Cooperative's members alone require 150,000 tons of organic alfalfa each year to keep their production at current levels. JA 647. While USDA has recently clarified that organic livestock must have a minimum of 120 days per year on pasture, *see* U.S. Department of Agriculture, National Organic Program; Access to Pasture (Livestock), 75 Fed. Reg. 7154 (February 17, 2010), the loss of a reliable supply of certified organic alfalfa would irreparably cripple the organic dairy industry. Farm management costs would dramatically increase, and the direct financial impact on organic dairy farmers due to lost domestic and international

markets would be in the hundreds of millions of dollars.

A. Gene Spread From Genetically Modified Organisms Has Destroyed Entire Markets For Organic Crops.

History has shown the catastrophic consequences to markets for organic or GE-free crops resulting from the infiltration of GE transgenes. These genes have proven uncontainable time and again, regardless of the preventative actions taken by regulators and farmers. In many cases, the contamination has caused widespread collapse of organic or non-GE markets in the United States and abroad.

Even the *risk* of contamination of organic alfalfa with RRA will have significant and immediate economic consequences for organic dairy farmers. *See* JA 243. Testing of alfalfa seed for the presence of the glyphosate-resistant gene costs $179 to $259 per sample, and some organic farmers would be forced to spend on the order of $25,000 annually just to verify that their alfalfa crops were free of GE transgenes. JA 648, 653-54. For companies like CROPP Cooperative, which pool milk supplies, every dairy farmer will have to test alfalfa on a regular basis to assure there is no contamination. Just months ago, in the wake of APHIS' release of its Draft EIS and based on its own comprehensive field testing, a major U.S. seed company noted to its customers that "[i]t is becoming clear that [the RR Alfalfa gene] . . . can easily spread

and that we are going to have to take extraordinary measures when producing foundation seed and commercial seed for GMO sensitive markets." Cal/West Seeds, *CW News*, Winter Issue 2010, *available at* http://www.regulations.gov/search/Regs/home.html#docketDetail?R=APHIS-2007-0044 (Docket Item No. APHIS-2007-0044-7617.2).

In 1995, Petitioner's genetically engineered species of glyphosate-resistant canola (*Brassica napus*), known as GT-73 or Roundup Ready canola, was among several GE canola varieties introduced in Canada following approval by the Canadian Food Inspection Agency. While it was understood by regulators that some gene spread could occur, the speed and extent of out-crossing among and between canola crops far surpassed even the most conservative predictions. *See, e.g.*, JA 859-60. Volunteer canola plants carrying GE traits were found in non-GE fields after only two seasons of commercial cultivation and occurred at distances of 800 meters in 2001 and 2500 meters in 2002. JA 859-60. Field studies conducted after the widespread planting of GE canola showed a remarkably rapid loss of biological purity in conventional *B. napus* cultivars. One study of pedigreed, non-GE canola found that 32 of 33 samples were in fact contaminated with GE varieties, some samples at levels of 2% or more. JA 872.

The economic consequences of this contamination were swift and severe, for seed sales as well as for Canadian organic and GE-free canola markets. The European market for organic canola from western

Canada disappeared virtually overnight when a major seed distributor acknowledged that conventional canola seed had been contaminated by GE canola prior to being sold to several EU countries. Stuart Smyth, et al., *Liabilities and Economics of Transgenic Crops*, 20 NATURE BIOTECHNOLOGY 6 (June 2002). Today, canola crops and oil from Western Canada cannot be marketed as organic or non-GE, and the small but once-burgeoning industry has collapsed. *See id.*; JA 139.

Similarly, the discovery of pervasive contamination of conventional rice by a GE variety known as LL601 caused a billion-dollar decline in European and other international markets for U.S. rice in 2006. *See* E. Neal Blue, *Risky Business: Economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandising system of the U.S.* (Greenpeace, 2007), *available at* http://www.greenpeace.org/raw/content/international/press/reports/risky-business.pdf. The widespread discovery of LL601 in global supplies of rice was described by industry experts at the time as "the most significant event in the history of the U.S. rice industry." Lisa Shumaker, *U.S. GMO Rice Caused $ 1.2 Billion in Damages* (Reuters News Service, November 5, 2007). Reflecting the near impossibility of comprehending, much less containing, the impacts of GE gene spread, a comprehensive USDA investigation ultimately failed to find the source of the contamination event. International markets responded rapidly to the news of the contamination; EU nations

ceased imports of U.S. rice, and futures prices for U.S. rice dropped ten percent in two days for a short term loss of $168,000,000. JA 884.

B. Organic Alfalfa Farmers Will Struggle To Meet USDA Organic Standards And Will Suffer Market Rejection If GE Alfalfa Is Widely Introduced.

Widespread planting of RR alfalfa imposes massive risk and uncertainty on the continued viability of organic dairy farming, due to the link between certified organic alfalfa used as feed by organic dairies. Contrary to Petitioners' assertion that organic alfalfa growers may market their crops as certified organic "regardless of any inadvertent cross-pollination," Pet.Br. 38, contamination of organic alfalfa could lead to the loss of organic certification.

To be marketed or sold as certified organic, alfalfa hay must be grown according to standards established by the USDA's National Organic Program ("NOP") under authority of the Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501 *et seq.* (2009) ("OFPA"). NOP regulations prohibit certified organic operations from using "excluded methods," which are "methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes. . . ." 7 C.F.R. §§ 205.105(e), 205.2. A producer of certified organic alfalfa may not use excluded methods, and under the NOP standards organic

dairies and other livestock facilities must use feed that is completely organic. There is no *de minimis* exception to the 100% organic feed requirement. *Id.* § 205.237(a). The Federal Respondents agree the matter is not so clear as Petitioners have described it. *See* Resp.Br. 27, n.6.

But regardless of the application of the NOP regulations, the values and choices of organic consumers will ultimately drive the market conditions for GE-tainted organic alfalfa and dairy products. As APHIS' Draft EIS for RRA explains, "one of the unique attributes of organic foods, and one reason consumer demand for organic foods is increasing, is the *intended absence* of GE ingredients in the process of producing them." U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Draft Environmental Impact Statement (November 2009) 60 ("Draft EIS"), *available at* http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gealfalfa_deis.pdf (emphasis added). Consumers in the U.S. organic market have identified the ability to avoid GE organisms as a leading reason for purchasing certified organic products. *See, e.g.*, JA 447, 705, 731. This consumer sentiment is reflected by the staggering number of public comments – in excess of 200,000 – received by APHIS on the Draft EIS, largely critical of its deregulation proposal. Without consumer confidence, the markets will fail even though the extent or degree of

GE contamination may be difficult to ascertain. JA 989-90.

Congress and the USDA have repeatedly sought to establish and protect meaningful organic standards in order to build consumer confidence and facilitate the growth of the market for certified organic products. The very purpose of OFPA is to "facilitate interstate commerce" in organically produced food, in part by establishing a regulatory program to "assure consumers that organically produced products meet a consistent standard[.]" 7 U.S.C. § 6501(2)-(3). Like the NEPA analysis itself, the scope of relief granted for a failure to comply with NEPA in this case ought to be consistent with and advance congressional purpose as established by OFPA. *See, e.g., Oregon Natural Desert Ass'n v. Bureau of Land Management*, 531 F.3d 1114, 1130 (9th Cir. 2008).

This risk of market rejection is even greater overseas. International markets for alfalfa will be notably more sensitive to the presence of GE transgenes due to their more stringent regulation of GE products and strong consumer demand for GE-free foods. JA 150, 243. Just five countries (Japan, Republic of Korea, Taiwan, Canada, and Mexico) account for 98% of the total metric tons of alfalfa exported. Japan, by far the leading importer of U.S. alfalfa hay, has a zero-tolerance policy for unapproved GE crops. Draft EIS at R-7, R-10, JA 430-35. For these reasons foreign importers of alfalfa hay, in Japan and elsewhere, are known to demand certainty from their American suppliers; in some cases, this demand for

certainty trickles down to U.S. alfalfa farmers who must alone bear the risk of GE contamination. *See, e.g.*, JA 239-44, 409-11, 420-23, 738.

II. THE LOWER COURTS CORRECTLY RECOGNIZED THAT ADDITIONAL RELEASE OF PETITIONER'S GENETICALLY ENGINEERED ALFALFA PRIOR TO FURTHER ENVIRONMENTAL REVIEW WOULD IRREPARABLY HARM THE ABILITY OF ORGANIC FARMERS TO CHOOSE TO MARKET ORGANIC PRODUCTS.

Amici desire to continue to grow, produce, and market organic products without GE organisms. But the unregulated release of RRA would irreparably harm that choice. As this Court stated in the antitrust context, prevention of "free choices between market alternatives is inherently destructive of competitive conditions" and deserving of condemnation "even without proof of its actual market effect." *Associated General Contractors of California v. California State Council of Carpenters*, 459 U.S. 519, 528 (1983). This same condemnation is deserved in evaluating the equitable factors involved with injunctive relief, where "[f]or those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop." Pet.App. 44a.

As described earlier, the organic industry is a vibrant, thriving sector of today's agricultural economy,

JA 407, 730-31, 741, 823, 989, whose very existence would suffer from additional unregulated release of RRA prior to further environmental review. The reports of actual instances of RRA contamination,[3] JA 419, 658, 663, 664, 666, 672; the history of organic (and, in some cases, conventional) market collapse following the planting of other GE crops, JA 112, 139; and the growth of contamination over time, JA 131, 693, 694, 696; all demonstrate that such a harm

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[3] Monsanto's argument that this evidence is "hearsay," Pet.Br 14, ignores the actual testing that was involved in some of this documentation. For example, Cal/West seeds, a seed grower, in describing a contamination event, stated that

> We first discovered the unintended presence of the Roundup Ready gene in our conventional alfalfa seed in 2005. It was identified in one of our foundation seed production lots grown in California. We tested the foundation seed lot prior to shipping it to a producer who intended to plant it for organic seed production. A representative sample of the seed lot was sent to a qualified lab and tested positive for the CP4EPSPS gene at the .01% level. The sample was tested again and was found positive at the .03%. After discovering that the foundation seed had been contaminated, we initiated tests on certified seed grown at three different field locations in Washington State using the same foundation seed lot. Seed from two of the three locations tested positive at the .01% level. The foundation seed was produced in 2003 in a field located in Solano County California. We didn't discover that it contained the Roundup Ready gene until after it had been used to plant the certified fields. Cal/West Seed had zero access to Roundup Ready seed at that time; therefore we assume the contamination originated from an external source

JA 672-73

would not be speculative, but instead significant and unremediable through traditional monetary damages. JA 112. Moreover, any new contamination will also damage organic farmers' ability to comply with the OFPA standards in a manner that cannot be repaired through the payment of damages. Injunctive relief was designed to avoid this very type of novel harm. Pet.App. 45a; *compare eBay, Inc. v. MercExchange, LLC*, 547 U.S. 388, 393 (2006) (criticizing a district court's denial of an injunction on the basis that the district court created too "broad [a] classification" when the district court concluded that a plaintiff's "lack of commercial activity in practicing the patent" suggested that the plaintiff patent holder lacked irreparable harm, instead pointing out that the loss of choice suffered by self-made inventors to license their patents to others might be sufficient for establishing irreparable harm) *with Winter v. Natural Resources Defense Council*, 129 S. Ct. 365, 376 (2008) (rejecting injunctive relief and pointing out that the activity that plaintiffs had sought to enjoin were training exercises that had been taking place in the same area for the last 40 years); *see also California v. American Stores Co.*, 492 U.S. 1301, 1307 (1989) (finding injunctive relief appropriate given the harm that would result to citizens from a substantial lessening of competition in the relevant market).

Consideration of harm to farmers' choice is consistent with the type of public interest that this Court has considered in the injunction context. In *Winter*, this Court considered the harm faced by the public if

the Navy were enjoined from engaging in its naval training operations. *See* 129 S. Ct. at 376-77 ("In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the remedy of injunction."); *see also id.* at 376-80. The harm faced by the public in this case is similarly significant – beyond even the irreparable harm suffered by the plaintiff farmers. If unregulated RRA is released without additional environmental review, not only would the plaintiff farmers be injured, but so would the public by losing its ability to choose to produce, buy, and sell organic products.

This harm to the public interest is cognizable even in the context of a NEPA injunction for two reasons: organic market choice is intertwined with impacts to the physical environment; and the harm to the public is similar to the public interest considerations in other NEPA injunction cases. As explained earlier, the market choices of organic growers, producers, and consumers and the environmental impacts are intertwined and predicated on minimizing underlying harm to the physical environment, due to the decreased off-farm inputs, reduced use of pesticides, and increased biodiversity through organic production management systems. *See* 7 C.F.R. § 205.2; *see also* Department of Agriculture, Agricultural Marketing Service, National Organic Program: Access to Pasture, 75 Fed. Reg. 7154, 7181 (February 17, 2010) (establishing stricter roles of pasture in organic livestock, including provisions to "protect[ ] natural

wetlands and riparian areas," that as a whole are "intended to satisfy consumer expectations that ruminant livestock animals graze on pastures during the grazing season"). Simply put, members of the organic community participate in the organic market in order to reduce their impacts on the environment. Thus the harm to market choice faced by the public falls well within the "effects" considered under NEPA, which "includes ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative." 40 C.F.R. § 1508.8 (defining the language of "effects" under NEPA). Moreover, the harm to market choices is one faced not only by the plaintiffs, but by all growers, producers, and consumers of organic products, and therefore part of necessary consideration of the public interest involved in assessing the propriety of any injunctive relief. *See Winter*, 129 S. Ct. at 380.

Indeed, the harm that the public faces here goes to the core of this country's respected values. The availability of market choice has always been one of the key freedoms respected by this Court. *See, e.g., FTC v. Ticor Title Insurance Company*, 504 U.S. 621, 632 (1992) ("The preservation of the free market and of a system of free enterprise without price fixing or cartels is essential to economic freedom."). Moreover, "the heart of our national economic policy long has been faith in the value of competition." *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951). The unregulated

release of RRA without additional environmental review would harm such competition – not through anticompetitive practices found illegal by this Court[4] – but through the physical destruction of the competitive products through contamination. The evidence presented to the district court states that one of the main reasons that individuals choose to be organic producers is because they desire to avoid genetically engineered crops, *see, e.g.*, JA 648, and that the unregulated release of RRA would result in loss of farmers' chosen livelihood of organic farming, *see, e.g.*, JA 649. Evidence in the record also attested to the difficulty of organic seed farmers selling contaminated seeds, JA 254, 549; the difficulty of farmers and producers in finding noncontaminated seeds, *see, e.g.*, JA 745-46, and organic feed, *see, e.g.*, JA 647-48; as well as the unavailability of measures for prevention of GE contamination, *see, e.g.*, JA 664, 693, 695. Finally, the record shows how contamination by RRA would devastate the reliance of organic consumers on organic certification because

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[4] Although at issue here is the physical destruction of competitive products – such as organic alfalfa and dairy products sustained by organic alfalfa – relevant to the public interest, rather than other aspects of anticompetitive practices also relevant to the public interest, these other anticompetitive concerns with Monsanto can also be seen in the U.S. Department of Justice's current antitrust investigation of Monsanto's seed pricing systems. *See, e.g.*, William Neuman, *Rapid Rise in Seed Prices Draws U.S. Scrutiny*, N.Y. TIMES B1 (March 12, 2010), *available at* http://www.nytimes.com/2010/03/12/business/12seed.html.

many of these consumers purchase organic products in order to avoid genetically engineered ingredients. *See, e.g.*, JA 649, 745, 824; *see also* Consumer Reports National Research Center, Organic Food Poll, at 3 (February 8, 2010), *available at* http://greenerchoices.org/pdf/OrganicFood%20Poll_Public%20Release_Feb%202010.pdf (stating that a "majority of respondents expressed some level of concern with contamination of organic food crops by genetic engineering"). All of this demonstrates the harm to economic choice faced by growers, producers, and consumers of organic products.

Petitioner attempts to downplay this harm by describing it as merely an economic loss, Pet.Br. at 38, rather than the type of harm considered in evaluating the appropriateness of injunctive relief. But no amount of money damages can compensate for this loss of choice for the general public. *Cf. Am. Trucking Ass'n v. City of Los Angeles,* 559 F.3d 1046, 1059 (9th Cir. 2009) (pointing out that economic loss so severe as to lead to the "loss of one's business" can constitute irreparable harm, even though irreparable harm is usually not demonstrated by economic loss alone). As this Court stated in *Business Electronics Corp. v. Sharp Electronics*, "The assumption that competition is the best method of allocating resources in a free market recognizes that all elements of a bargain – quality, service, safety, and durability – and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers." 485 U.S. 717, 757 (1988) (quoting *National Society of Professional Engineers v. United States*, 435

U.S. 679, 695 (1978)). Depriving consumers of the ability to choose between GE and non-GE alfalfa will permanently alter the market's structure, and prevent a full and fair competition between GE and non-GE alfalfa in the marketplace. This artificial inhibition of competition will permanently disrupt the market's natural evolution in ways that are impossible to fully predict. *See generally Summit Health, Ltd. v. Pinhas*, 500 U.S. 322, 331 n.11 ("The federal power to protect the free market may be exercised to punish conduct which threatens to impair competition even when no actual harm results") (quoting favorably *United States v. Staszcuk*, 517 F.2d 53, 60, n.17 (7th Cir. 1975).

Finally, Petitioner's suggestion that non-RRA is merely another "varietal" whose "purity" can be maintained "through well-established stewardship techniques," Pet.Br. 1-2, is similarly misleading. First, evidence on the record demonstrates the current difficulties of preventing GE contamination that go well beyond varietal contamination, *see, e.g.*, JA 664, 693, 695. Next, the price premium commanded in the market place by organic products, JA 823 – considered to be GMO-free by consumers – indicates that consumers consider non-RRA to be a distinct product market from RRA varietals, which do not command a similar price premium.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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April 5, 2010.

AMICUS CURIAE BRIEF

No. 09-475

In The Supreme Court of the United States

MONSANTO COMPANY, ET AL.,

Petitioners,

v.

GEERSTON SEED FARMS, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR *AMICI CURIAE* DEFENDERS OF WILDLIFE, HUMANE SOCIETY OF THE UNITED STATES, AND THE CENTER FOR BIOLOGICAL DIVERSITY IN SUPPORT OF RESPONDENTS

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INTERESTS OF *AMICI CURIAE*[1]

Amici are non-profit conservation and animal protection organizations with longstanding interests in the effective implementation of the National Environmental Policy Act of 1969 ("NEPA"), 42 U.S.C. §§ 4321-4370f, and other environmental statutes, particularly with regard to ensuring that federal agencies adequately consider the actual and potential effects of their actions on the natural environment, including wildlife and plants.

Defenders of Wildlife ("Defenders") is a non-profit organization with over one million members and supporters across the country. Defenders is dedicated to the protection and restoration of all native wild animals and plants in their natural communities.

The Humane Society of the United States ("HSUS") is the nation's largest animal protection organization. HSUS has over eleven million members and constituents across the country, and is dedicated to the protection of all animals, including wildlife, through education, advocacy, and hands-on programs.

The Center for Biological Diversity ("CBD") is a national non-profit membership organization that

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[1] No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief No persons other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

strives to secure a future for animals and plants hovering on the brink of extinction. On behalf of its more than 225,000 members and supporters, CBD is actively involved in species and habitat protection advocacy throughout the United States.

Amici seek to protect and restore the natural environment through participation in administrative proceedings before government agencies, litigation in federal court, and public education activities. In carrying out these activities, *amici* and their members participate extensively in NEPA processes pertaining to federal agency actions that may significantly affect wildlife and plants, including by commenting on Environmental Impact Statements ("EISs") and Environmental Assessments ("EAs") that address environmental effects of federal actions. In addition, when the NEPA process is not implemented sufficiently to consider an adequate range of alternatives or to otherwise take a hard look at environmental impacts, *amici* rely on litigation to ensure that NEPA's purposes are fulfilled. The positions advanced by petitioners here would, if adopted by the Court, greatly impede the ability of *amici* to rely on NEPA to ensure a meaningful consideration by federal agencies of the impacts of their actions on the environment, and particularly wildlife and plants.

BACKGROUND

To illuminate the narrow nature of the controversy here, it is necessary at the outset to highlight two crucial aspects of this case that are not seriously addressed in either the petitioners' or the government's brief, but that should bear heavily on the issues that Monsanto does raise.

First, petitioners expound at length on their view that the large-scale introduction of genetically-modified alfalfa (called Roundup Ready Alfalfa, or "RRA") into the environment will have no adverse environmental impacts, describing as "bad science fiction," Petitioners' Brief (Pet. Br.) at 34, the very environmental concerns that the district court found warranted an EIS pursuant to NEPA. However, no party in this case is challenging the district court's Order finding that an EIS must be prepared under the circumstances here. *See* Pet.App.108a; Pet. Br. at 9 (explaining that the district's court order requiring an EIS "is not challenged here"); Government's Brief ("Gov't Br.) at 11-12 (noting that "[n]o appellant challenged the district court's merits determination").

Hence, it is uncontested that the underlying agency action at issue – the deregulation of RRA, thereby allowing the crop to be planted anyplace and at any time, *see* 70 Fed. Reg. 36,917 (June 27, 2005) – at least poses environmental hazards sufficient to warrant a full-blown EIS, rather than the EA that the United States Department of Agriculture ("USDA") had prepared and originally defended in the district

court. Indeed, as the government points out, in compliance with the district court ruling, an EIS *is* being prepared at this time. Gov't Br. at 14.

But this concession on the underlying merits of the NEPA claim is crucial because, as this Court has previously recognized, NEPA requires an agency to prepare an EIS "*only* if it will be undertaking a 'major Federal actio[n]' which 'significantly affect[s] the quality of the human environment.'" *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 763 (2004) (quoting 42 U.S.C. § 4332(c) (emphasis added)); *see also Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 772 (1983) ("where an agency action significantly affects the quality of the human environment, the agency must evaluate the 'environmental impact' and any unavoidable adverse environmental effects of its proposal"). Thus, there is a fundamental disconnect between Monsanto's and the government's acquiescence in the district court's ruling that potential environmental impacts *are* sufficiently significant to warrant an EIS, and their simultaneous insistence that the agency action as to which that EIS is being prepared carries no meaningful environmental risks at all.

Second, having determined that the agency violated NEPA, and hence the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, by failing to prepare an EIS before making its deregulation determination, the district court *vacated* the agency's determination in accordance with the plain terms of the APA. *Id.* at § 706(2); Pet.App.58a. The legal effect of that vacatur

order was to render the planting of RRA unlawful under the agency's regulatory scheme. *See* 7 C.F.R. § 340.0(a). However, neither Monsanto nor USDA has challenged *that* element of the relief awarded below, let alone argued that the district court was obligated to conduct a separate trial-type proceeding on irreparable injury before awarding the standard APA relief for agency actions that have been adopted in violation of federal law.

This unchallenged feature of the relief is also critical here because the "injunction" that Monsanto so vigorously opposes actually had no practical effect beyond that accomplished by vacatur of the agency action pending completion of the EIS. In other words, either the petitioners are attempting to launch a back-door challenge to the vacatur, which should not be allowed at this late date, or they are complaining about an injunction that merely forbids them from doing that *which they could not lawfully do in any event* as a direct consequence of the vacatur as to which they are *not* objecting. In either event, it is highly problematic for all of petitioners' arguments that, although petitioners purport to be challenging only the district court's *injunctive relief*, they would be in essentially the same legal and practical posture *without* that specific relief having been awarded.

SUMMARY OF ARGUMENT

1. NEPA claims are resolved under the APA, pursuant to which a court must typically "set aside" unlawful agency action, often accompanied by remand to the agency for further investigation or explanation. 5 U.S.C. § 706(2); *see also Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). When a court, as here, vacates an unlawfully adopted agency action pending compliance with federal law, no separate proceeding on irreparable injury is required, and petitioners here advance no argument or precedent to the contrary.

That the district court could (and did) vacate USDA's deregulation decision pending compliance with NEPA has important consequences for the proper resolution of this case. In sharp contrast to a situation in which a court's injunctive relief extends far beyond the traditional APA relief authorized by 5 U.S.C. § 706(2) – and hence in which some further analysis of irreparable injury or a balancing of equities may be appropriate – here the injunction that petitioners object to merely took the district court's unchallenged vacatur order (which by operation of law made the planting of RRA illegal pending issuance of an EIS) and framed essentially the same relief as an injunction applicable to the parties before the Court. *See* Pet.App.10a. Conspicuously, however, petitioners do not articulate what, if anything, they were prevented from doing by virtue of the injunction that they would have been legally permitted to do in the aftermath of vacatur alone. In the absence of such

an explanation, petitioners' protestation that the lower courts fashioned some draconian relief without taking into account the necessary equitable factors or following the correct process rings hollow.

Moreover, especially in a situation in which a court has done little more than effectuate vacatur of an unlawful agency action, a separate trial-type proceeding on remedies for cases arising under the APA – which must generally be resolved on an administrative record, and without the need for live witnesses – makes little legal, logical, or practical sense. It makes even less sense when the underlying claim concerns a failure to prepare an EIS in compliance with NEPA, since the purpose of the EIS process is to consider essentially the same issues that the court would have to address in an evidentiary hearing. Such overlapping proceedings would not only detract from the agency's ability to complete the required EIS – especially if, as would often be the case, one or more of the parties would seek testimony from the very same agency experts responsible for preparing the EIS – but would also potentially place the trial court and the agency in the untenable position of coming to conflicting conclusions, during essentially the same time frame, on the nature and degree of harm posed by a particular environmental impact.

In addition to encroaching on the role assigned by Congress to the executive branch agency, such parallel proceedings would necessitate extensive remedy trials – preceded, presumably, by, *e.g.*, expert reports, depositions, document requests, and other forms

of discovery – that ordinarily have no role in an APA case and that would dramatically increase the amount of time that federal courts must spend on NEPA cases, of which there are many pending in the federal courts.[2] There is at present no precedent that demands such an increase in the workload of already overburdened federal trial judges, and this Court should be loathe to create one here. *Cf. Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (noting that even when substantial property interests are implicated, it is rare that district courts initiate evidentiary hearings "closely approximating a judicial trial"); *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972) (recognizing the flexibility district courts ordinarily have to determine what process is due under the particular circumstances of a case).

2. The assertion by Monsanto and the government that an impact on a wildlife or plant species may only be deemed "irreparable" if the plaintiffs can prove "species-level harm," Pet. Br. at 36-37; Gov't Br. at 28-29, is not only totally unnecessary to the resolution of this case, but is also legally groundless. As this and other courts have long recognized, the analysis of irreparable injury in the wildlife context turns not only on the specific statutory provisions at issue, but also on the nature of the injury inflicted on

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[2] For example, in 2008 alone, 132 NEPA cases were filed in federal district courts, bringing the total nationwide number of pending NEPA cases to 233. http://ceq.hss.doe.gov/nepa/nepa_2008litigationsurvey.pdf.

the *plaintiffs. See Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 374 (2008). Just as plaintiffs may be irreparably injured by the destruction or degradation of a particular forest they enjoy although forests may exist elsewhere, plaintiffs may also be irreparably harmed by the loss or impairment of wildlife they enjoy or benefit from in a particular location regardless of whether the wildlife species is abundant elsewhere. *E.g.*, *Greater Yellowstone Coal. v. Flowers*, 321 F.3d 1250 (10th Cir. 2003) (finding irreparable injury to plaintiffs' interests under NEPA based on harm to bald eagles in a particular location enjoyed by plaintiffs).

Thus, where plaintiffs have concrete aesthetic, recreational, or other interests in wildlife or plant species in specific refuges, parks, forests, or other natural areas, plaintiffs' demonstration of a significant impact on or threat to *those concrete interests* by virtue of the government's failure to prepare an EIS before the harmful action ensues should be sufficient to establish irreparable injury irrespective of any potential species-wide impact stemming from such activities. *Cf. Lujan v. Defenders of Wildlife*, 504 U.S. 555, 572 (1992) (plaintiffs may "seek[ ] to enforce a procedural requirement the disregard of which could impair a separate concrete interest of theirs (e.g., . . . the procedural requirement for an [EIS] before a federal facility is constructed next door to them"). Accordingly, there is no legal basis for a holding that species-level harm is necessary to establish irreparable injury whenever plaintiffs complain about

NEPA violations in connection with federal actions that impact wildlife or plant species.

ARGUMENT

I. WHERE, AS HERE, AN AGENCY DECISION HAS BEEN VACATED PURSUANT TO THE APA ON THE GROUNDS THAT THE DECISION VIOLATED NEPA, AND A CHALLENGED INJUNCTION IMPOSES NO DISCERNIBLE BURDEN BEYOND THE VACATUR, PETITIONERS' ARGMENT THAT THEY WERE ENTITLED TO A SEPARATE PROCEEDING ON IRREPARABLE INJURY MAKES NO LEGAL OR LOGICAL SENSE.

A. Upon Finding A Legal Violation, A Court May Vacate An Agency Action Without Looking Beyond The Administrative Record And Without The Plaintiffs Meeting The Same Burden That Applies To The Crafting Of Injunctive Relief.

The Court would not know it from Monsanto's brief – which, remarkably, does not cite the APA even once, *see* Pet. Br. at Table of Authorities – but this case, as with most cases seeking relief for violations of NEPA, was brought pursuant to the APA, and hence is governed by the APA's standard of review and other directives. *See, e.g.*, *Sierra Club v. Slater*, 120 F.3d 623, 631 (6th Cir. 1997) (because NEPA has no private right of action "federal courts have jurisdiction over NEPA challenges pursuant to the APA").

As with other APA claims, NEPA claims are generally resolved based on the administrative record that was before the agency at the time of its decision, rather than some new evidentiary record compiled in the district court in the first instance. *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 419-420 (1971).

In addition, and of particular importance to the relief issues raised by Monsanto, the APA provides that if, based on a review of the administrative record, a reviewing court concludes that an agency action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or that the action has been adopted "without observance of procedure required by law," the reviewing court "*shall* . . . hold unlawful and set aside" – *i.e.*, order vacatur of – the agency action. 5 U.S.C. § 706(2)(A) (emphasis added); *see also Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998) ("[T]he mandatory 'shall' . . . normally creates an obligation impervious to judicial discretion.").

In view of the plain terms of the APA, the "normal course of action" followed by this Court and other federal courts has been to do what the APA says:

> [f]or most of the relatively brief history of administrative law, the court's proper course when it deems an action unlawful has been considered self-evident: the court declares the action void and sends it back to the agency for further consideration.

Ronald M. Levin, *'Vacation' At Sea: Judicial Remedies and Equitable Discretion in Administrative Law*, 53 Duke L.J. 291, 294 (2003); *id.* at 309 (a "literal reading of section 706 . . . says that a court 'shall' set aside an agency action found to be unlawful"); *see also Comcast Corp. v. FCC*, 579 F.3d 1, 10 (D.C. Cir. 2009) (Randolph, J., concurring) ("Section 706(2)(A) of the APA could not be clearer: a court faced with an arbitrary and capricious agency rule . . . 'shall hold unlawful and set aside' that agency action. 'Set aside' means vacate, according to the dictionaries and the common understanding of judges") (quoting 5 U.S.C. § 706(2)(A)). Indeed, this Court has stated that "[i]n all cases *agency action must be set aside* if the action was 'arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law.'" *FCC v. Nextwave Personal Commc'ns*, 537 U.S. 293, 300 (2003) (citation omitted) (emphasis added); *id.* ("The [APA] requires federal courts to set aside federal agency action that is 'not in accordance with law,' which means, of course, *any* law, and not merely those laws that the agency itself is charged with administering.") (internal citation omitted); *see also Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976) ("if the decision of the agency 'is not sustainable on the administrative record made, then the . . . decision must be vacated and the matter remanded'") (citation omitted).

As respondents explain, Respondents' Brief ("Resp. Br.") at 19-24, petitioners did *not* object to the vacatur of the deregulation decision in the courts below,

and they say nothing about it in their brief to this Court. Accordingly, this omission is not only fatal to petitioners' standing, *id.*, but it also completely undermines Monsanto's arguments concerning the standards and process that petitioners maintain should have been applied before "injunctive" relief was fashioned. Simply put, since Monsanto advances no argument concerning the legal validity of the vacatur – which itself rendered unlawful the conduct Monsanto seeks to pursue until a new decision is made following NEPA compliance – Monsanto cannot reasonably (or even sensibly) contend that some extensive trial-type proceeding on irreparable injury (or other equitable factors) should have been conducted before the district court issued injunctive relief that merely mirrors the *uncontested* vacatur.[3]

Given the legal corner into which it has painted itself, it is difficult to discern how Monsanto could prevail here without attempting to argue in its reply brief that *because* the district court's vacatur had essentially the same practical effect as the injunction, the district court should have required some further showing of irreparable injury, or held a trial-type proceeding, before merely setting aside the deregulation

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[3] As respondents note, the district court essentially crafted injunctive relief that afforded respondents *less* relief than that afforded by complete vacatur of the deregulation decision. *See* Resp. Br. at 20 n. 11. Monsanto surely cannot complain about an injunction that had *less* practical impact on alfalfa planting than the vacatur remedy authorized by the plain terms of the APA.

decision. But any such argument should not only be emphatically rejected on waiver and timeliness grounds, it would also fly in the face of elementary APA principles. This Court has certainly never suggested that injunction-type standards must be met or trial-type proceedings pursued before reviewing courts in APA cases may set aside unlawfully adopted agency decisions pursuant to the plain terms of 5 U.S.C. § 706(2).

Nor is there any precedent for such a holding in the lower courts. For example, although the D.C. Circuit has authorized remand without vacatur in some circumstances, it has repeatedly characterized vacatur as the "ordinary result," *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998), the "normal[]" approach to APA review, *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001), and the courts' usual "responsibility under the APA" when it discerns that an agency action has been adopted in violation of federal law. *Md. Pharm., Inc. v. DEA*, 133 F.3d 8, 16 (D.C. Cir. 1998). And even when the D.C. Circuit has departed from that presumptive remedy, it has never suggested that those who have successfully challenged the legality of agency action must satisfy some additional stringent standard merely to accomplish the relief that the plain language of the APA authorizes. Rather, that court has appropriately placed the burden *on the agency* to demonstrate that special circumstances justify departing from the APA's plain terms. *E.g.*,

Chamber of Commerce of the United States v. SEC, 443 F.3d 890, 908 (D.C. Cir. 2006).[4]

Moreover, in deciding whether to issue the APA's standard relief of vacatur, the D.C. Circuit (and other federal courts) have certainly never suggested that an evidentiary hearing is necessary or appropriate. To the contrary, when the D.C. Circuit sets aside agency action that has been found to violate the APA's standard of review – including because the agency violated NEPA – it generally does so as a matter of course, and with no extended analysis.[5] Therefore,

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[4] As one member of the D.C Circuit has explained, a vacatur order provides the agency with much stronger incentives to remedy the defects in a rulemaking or other agency decision than a remand-only remedy, which allows the agency to continue to act under its defective rule. *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring) (awarding mandamus relief where agency had refused to act on a remand without vacatur). Of course, a court may award vacatur and then consider whether to *stay* that order in whole or in part in light of equitable considerations. *E.g. Honeywell Int'l Inc. v. EPA*, 374 F.3d 1363, 1375 (D.C. Cir. 2004) (Randolph, J., concurring). Once again, however, the *agency* must establish that the standards for a stay are satisfied, including that there "will be irreparable harm without the stay. . . ." *Id.*; *see also Natural Res. Def. Council v. EPA*, 489 F.3d 1250, 1264 (D.C. Cir. 2007) (Randolph, J., concurring) (in an analysis of whether vacatur should be stayed, explaining that the "burden is where it should be – on the losing agency").

[5] *See, e.g., Dillmon v. NTSB*, 588 F.3d 1085, 1095 (D.C. Cir. 2009) ("[B]ecause the Board departed from its precedent without reasoned explanation, we grant the petition for review, vacate the order, and remand for further proceedings."); *Am. Bird Conservancy, Inc. v. FCC*, 516 F.3d 1027, 1033-35 (D.C. Cir.

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any notion that a reviewing court must hold a separate proceeding on irreparable injury (or other equitable considerations) before vacating an action under the APA would be a stark departure from the long-standing practices of the federal courts. *See, e.g.*, *Lorion*, 470 U.S. at 744 (emphasizing that a "formal hearing . . . is in no way necessary" under the APA, and that "[t]he APA specifically contemplates judicial review on the basis of the agency record compiled in the course of [proceedings] in which a hearing has not occurred").[6]

2008) (vacating an FCC order concerning the effect of communications towers on birds because the "[o]rder fails to follow the Commission's own regulations implementing NEPA"); *Ramaprakash v. FAA*, 346 F.3d 1121, 1130 (D.C. Cir. 2003) (Roberts, J.) ("Where an agency departs from established precedent without a reasoned explanation, its decision will be vacated as arbitrary and capricious.") (internal citation omitted); *Davis County Solid Waste Mgmt. v. EPA*, 101 F.3d 1395, 1411 (D.C. Cir. 1996) (holding that "we have no choice but to vacate substantial portions of the 1995 standards, based on our conclusion that they exceed the EPA's authority").

[6] It also bears noting in this regard that courts of appeals often have original jurisdiction over review of agency action, and requiring extended proceedings on the equities to resolve among basic APA forms of relief would be wholly inconsistent with Congress' decision to vest original jurisdiction in the courts of appeals for such claims. Indeed, even where petitioners challenge an agency's *failure* to act under the APA, 5 U.S.C. § 706(1), claims which necessarily implicate facts that may go beyond the confines of an administrative record – such as, *e.g.*, the consequences of delay for the public interest and "the effect of expediting delayed action on agency activities of a higher or competing priority," *Telecommunications Research & Action Center v. FCC*,

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In sum, because petitioners are *not* challenging the vacatur of the deregulation order – and they have advanced no argument whatsoever that the district court abused its discretion merely by doing what the APA authorizes – they must lose on the grounds that the district court's "injunction" had no discernible impact on them beyond that flowing from the vacatur itself. On the other hand, if petitioners *had* timely challenged the vacatur along with the injunction, they would lose on the alternate grounds that the lower courts acted well within their discretion in abiding by the "shall . . . set aside" proviso in the APA while USDA brought itself into compliance with NEPA's EIS requirement. *See* 5 U.S.C. § 706(2). In any event, petitioners' confused legal position hardly warrants a sweeping ruling by this Court on the nature of relief in NEPA cases specifically, or APA cases generally.[7]

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750 F.2d 70, 80 (D.C. Cir. 1984) – courts of appeals routinely resolve such claims without resort to trial-type proceedings. *Id.* at 80-81 (rejecting the suggestion that appellate review of mandamus claims "may be inadequate due to Courts of Appeals' inability to take evidence").

[7] Although petitioners rely heavily on this Court's ruling in *Winter*, that case simply did not involve a comparable legal situation in which a court had vacated a final agency action in accordance with the APA. Indeed, in that case – which involved the propriety of a preliminary injunction challenged by the Navy on national security grounds – the Court stressed that the NEPA challenge involved "training exercises that have been taking place . . . for the last 40 years," 129 S. Ct. at 376, rather than

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B. As A General Matter, NEPA's Purposes Are Best Served When The Regulatory And Environmental Status Quo Is Maintained While An Agency Prepares A Legally Mandated EIS.

Since petitioners have not challenged vacatur of the deregulation decision, and in any case that relief is fully supported by the plain terms of the APA and the case law construing it, the Court need not go further in addressing what is essentially an academic discourse in *this* case on the appropriate standards and procedures for injunctive relief in NEPA challenges. But if the Court does address that issue, NEPA's overarching purposes should play a central role in the Court's analysis.

While respondents have pinpointed the many errors in petitioners' assertion that the lower courts improperly relied on a "NEPA exception" to the traditional injunction standards, and respondents have also explained that the district court did *not* craft equitable relief based simply on the NEPA violation the court discerned, Resp. Br. at 30, it is also the case that maintaining the environmental and regulatory status quo pending preparation of a required EIS – through vacatur, an injunction, or a combination of both – is ordinarily essential to the accomplishment of NEPA's purposes. By the same token, to allow an

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any discrete final agency action that was susceptible to vacatur under the APA.

agency action to be implemented while the same action is supposedly being studied in a legally required EIS will, as a general rule, make a total mockery of the statutory scheme crafted by Congress. Taking these realities into account in addressing the relief issue in a NEPA case comports fully with this Court's approach to injunctive relief in other environmental cases.

As this Court has instructed, and as the government recognizes, *see* Gov't Br. at 30, in evaluating whether to craft equitable relief to remedy a particular statutory violation, a reviewing court must consider the extent to which such relief is appropriate in light of the "purpose and language of the statute under consideration." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 314 (1982); *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 496-98 (2001); *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 541-43 (1987); *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 173 (1978). For example, in *Weinberger*, the Court upheld the district court's discretion to determine that a particular violation of the Federal Water Pollution Control Act ("FWPCA"), 33 U.S.C. §§ 1251-1387 – which involved the Navy's discharge of ordnance into the ocean – did not need to be remedied by an immediate injunction against such discharges because the "purpose" of the FWPCA, to protect the "integrity of the Nation's waters," could be achieved through relief *other than an injunction*, namely, an order directing the Navy to apply for a permit. 456 U.S. at 314-15 ("The integrity of the

Nation's waters, however, not the permit process, is the purpose of the FWPCA .... [A]though the District Court declined to enjoin the discharges, *it neither ignored the statutory violation nor undercut the purpose and function of the permit system.*") (emphasis added).

Likewise, in *Amoco Prod. Co. v. Vill. of Gambell, Alaska*, the Court held that a finding of a likely violation of the Alaska National Interest Lands Conservation Act ("ANILCA"), 16 U.S.C. § 3120, did not necessitate the issuance of preliminary injunctive relief because the "underlying substantive policy the [ANILCA] process was designed to effect – preservation of subsistence resources" for Alaskan natives – could be served without enjoining the oil and gas exploration activities at issue. 480 U.S. 531, 544 (1987). While observing that generally "[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable," and that "[i]f such injury is sufficiently likely, therefore, the balance of harms will usually favor the issuance of an injunction to protect the environment," in that case, the district court had made the factual determination that the "exploration activities would not significantly restrict subsistence uses," and hence injunctive relief was not needed to accomplish the "underlying substantive policy" embodied in ANILCA. *Id.* at 544-45.

As these and other precedents hold, therefore, a court's injunction analysis cannot occur in a legal vacuum; rather, although district courts must

determine whether injunctive relief is appropriate under the particular facts of the case, they must also consider whether the statutory purpose can meaningfully be furthered by relief other than that which maintains the *status quo* while the legal violation is being addressed. Indeed, this Court has stressed that a "court sitting in equity cannot 'ignore the judgment of Congress, deliberately expressed in legislation,'" and hence it is the court's role to assess whether the "selection of an injunction *over other enforcement mechanisms*" is appropriate to effectuate the particular scheme adopted by Congress. *Oakland Cannabis Buyers' Coop.*, 532 U.S. at 497-98 (emphasis added) (citation omitted); *cf. Weinberger*, 456 U.S. at 314 (explaining that, in *Hill*, 437 U.S. 153, the Court had determined that the "purpose and language of the [Endangered Species Act] limited the remedies available to the District Court").

When this analysis is applied to NEPA, it dictates the conclusion that plaintiffs in NEPA cases surely satisfy the irreparable injury element of the test for injunctive relief when, as here, they establish that (1) an agency has failed to prepare an EIS that is required by law, and (2) the statutory violation is accompanied by a "significant risk" of harm to the environment that implicates plaintiffs' concrete interests in affected resources. *Greater Yellowstone Coal.*, 321 F.3d at 1261. Once again, an EIS is required *only* when an action threatens significant environmental harm. *See supra* at 4. Moreover, given NEPA's unique "purpose and language," *Weinberger*, 456 U.S.

at 314, in most cases, it is simply impossible for the statutory scheme to be carried out as Congress intended unless the *status quo* is maintained during the time that a legally mandated EIS is being prepared. Consequently, where (as here) a reviewing court has made a final, unchallenged determination that an EIS is required by law, *and* the plaintiffs have established that *their* interests are threatened by the very environmental impacts and risks that necessitate preparation of the EIS, that should ordinarily be sufficient to maintain the *status quo* while the EIS is being prepared, at least unless overriding equitable factors dictate a contrary result.[8]

Thus, as the Court explained in *Winter*, NEPA imposes purely "procedural requirements to ensur[e] that the agency, *in reaching its decision*, will have available, and will carefully consider, detailed information concerning significant environmental impacts." *Winter*, 129 S. Ct. at 376 (citations omitted; emphasis added). Those procedural safeguards are "intended to reduce or eliminate environmental damage and to promote 'the understanding of the ecological systems and natural resources important to' the United States."

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[8] In this case, the significant environmental risks that warrant preparation of an EIS, and that also implicate respondents' interests in particular, involve not only whether RRA would further contaminate conventional alfalfa (as it already has), *see* Resp. Br. at 6-15, but also the risk that large-scale use of RRA will dramatically increase the use of the Roundup pesticide, Pet.App.48a, which, among other impacts, may result "in the development of Roundup-tolerant weeds." Pet.App.45a.

Pub. Citizen, 541 U.S. at 756 (quoting 42 U.S.C. § 4321).

However, in contrast to substantive environmental statutes like those at issue in *Weinberger* and *Village of Gambell*, "'NEPA itself does not mandate particular results' in order to accomplish" its goal of increased environmental protection. *Id.* at 756 (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989)). Instead, the "NEPA EIS requirement" is designed to inject environmental considerations "in the agency decisionmaking process itself," and to "'help public officials *make decisions that are based on understanding of environmental consequences*, and take actions that protect, restore, and enhance the environment.'" *Id.* at 768-69 (emphasis added) (quoting 40 C.F.R. § 1500.1(c)).[9]

Because "NEPA's core focus [is] on improving agency decisionmaking," *Pub. Citizen*, 541 U.S. at 769 n. 2, and specifically on ensuring that agencies take a "hard look" at potential environmental impacts and environmentally enhancing alternatives "as part of the agency's process of deciding whether to pursue a

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[9] *See also Robertson*, 490 U.S. at 349 (The EIS requirement "ensures that the agency, in reaching its decision, will have available, *and will carefully consider*, detailed information concerning significant environmental impacts") (emphasis added); 40 C.F.R. § 1502.1 ("The primary purpose of an environmental impact statement is to serve as an action-forcing device to insure that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government.").

particular federal action," *Baltimore Gas and Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 100 (1983), the "moment at which an agency must have a final statement ready 'is the time at which it makes a recommendation or report on a *proposal* for federal action.'" *Kleppe v. Sierra Club*, 427 U.S. 390, 406 (1976) (emphasis in original) (quoting *Aberdeen & Rockfish R. Co. v. Students Challenging Regulatory Agency Procedures*, 422 U.S. 289, 320 (1975)); *see also* 42 U.S.C. § 4332(C). This requirement is designed to "place[ ] upon an agency the obligation to consider every significant aspect of the environmental impact" at a stage when such impacts can most meaningfully influence the agency's deliberations, *i.e.*, after the agency has settled on a "proposed action," but *before* any decision and its environmental effects are a *fait accompli*. *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council*, 435 U.S. 519, 553 (1978).[10]

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[10] *See also Andrus v. Sierra Club*, 442 U.S. 347, 351 (1979) (the CEQ regulations "require federal agencies to 'integrate the NEPA process with other planning at the earliest possible time to insure that planning and decisions reflect environmental values'") (quoting 40 C.F.R. § 1501.2); *Flint Ridge Dev. Co. v. Scenic Rivers Ass'n of Okla.*, 426 U.S. 776, 787 (1976) ("NEPA's instruction that all federal agencies comply with the impact statement requirement and with all the other requirements of § 102 'to the fullest extent possible,' 42 U.S.C. § 4332, is neither accidental nor hyperbolic. Rather, the phrase is a deliberate command that the duty NEPA imposes upon the agencies to consider environmental factors not be shunted aside in the bureaucratic shuffle.").

This Court's longstanding recognition of NEPA's fundamental "action-forcing" function of ensuring that "environmental concerns are . . . interwoven into the fabric of agency planning," *Andrus*, 442 U.S. at 351, has important implications for whether the environmental and regulatory *status quo* should ordinarily be maintained while a legally mandated EIS is being prepared. Although there may be unusual circumstances compelling a contrary result, *see Winter*, 129 S. Ct. at 381 (finding that national security considerations dictated that naval training exercises proceed notwithstanding a likely NEPA violation), as a general matter, for a court to allow an agency action to be implemented while an EIS is being prepared renders NEPA compliance a make-work exercise and "makes a mockery of the EIS process, converting it from analysis to rationalization." Leslye A. Herrmann, *Injunctions for NEPA Violations: Balancing the Equities*, 59 U. Chi. L. Rev. 1263, 1289 (1992).

As this Court has stressed time and again, that is precisely what Congress did *not* intend when it imposed the EIS obligation on federal agencies. *See Pub. Citizen*, 541 U.S. at 768-69 (rejecting the concept of NEPA compliance that can have "no effect" on agency decisionmaking because "'*NEPA's purpose is not to generate paperwork – even excellent paperwork – but to foster excellent action*'") (quoting 40 C.F.R. § 1500.1(c) (emphasis added); *see also Andrus*, 442 U.S. at 351 n. 3 (explaining that an EIS must be "prepared early enough so that it can serve practically as an important contribution to the decisionmaking process and

will not be used to rationalize or justify decisions already made") (emphasis added); *Baltimore Gas and Electric Co.*, 462 U.S. at 100 ("Congress did not enact NEPA, of course, so that an agency would contemplate the environmental impact of an action as an abstract exercise."). Moreover, allowing an agency to implement an action before the agency has completed a legally required EIS not only renders the EIS the "abstract exercise" Congress wanted to avoid, *id.*, but it also affords prevailing NEPA plaintiffs who are directly threatened by the action (as are respondents here) with *no meaningful remedy at all* – a result that should generally be avoided. *See Oakland Cannabis Buyers' Coop.*, 532 U.S. at 497-98.[11]

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[11] For these reasons, it is commonplace for federal courts throughout the country to maintain the *status quo* pending agencies' compliance with NEPA, particularly when allowing the agency action to go forward will foreclose alternative courses of action that may entail less environmental damage and that the agency might elect to adopt based on its "hard look" in an EIS. *See* Daniel R. Mandelker, *NEPA Law and Litigation, 2d*, at § 4:61 (2008) ("In the usual case in which the court grants a preliminary injunction, it enjoins all further work until an adequate impact statement has been prepared or NEPA responsibilities have been met . . . .") (citing cases from the Second, Fourth, Eighth, and Ninth Circuits); *see also* William Rodgers, *Environmental Law* § 7.7 at 767 (1977) ("[NEPA's] purpose is to require consideration of environmental factors *before project momentum is irresistible, before options are closed, and before agency commitments are set in concrete.*") (emphasis added); 42 U.S.C. § 4332(C)(iii) (requiring that EIS's address "alternatives to the proposed action").

Indeed, notwithstanding their insistence that respondents did not demonstrate the requisite irreparable injury to warrant the issuance of equitable relief, petitioners' ultimate request, paradoxically, is that the Court *should* order that such relief be issued – albeit a narrower remedy than the one adopted by the district court. Presumably, this is because even petitioners recognize the peculiarity of a holding that an agency action should proceed unabated *before* a legally mandated EIS has been completed. In any event, when the "purpose and language of the statute under consideration" are brought to bear on the remedy issue, *Weinberger*, 456 U.S. at 314, they strongly suggest that, in the routine NEPA case (such as this one), if the environmental impacts and risks associated with an agency action are significant enough to warrant an EIS informing the agency's views on *whether and how to proceed with the action* – as is unchallenged by petitioners here – and if the plaintiffs demonstrate that their interests are threatened by the very impacts and risks being scrutinized in the EIS, then the plaintiffs have established sufficient irreparable injury to maintain the *status quo* until the agency has informed its decisionmaking in the manner mandated by federal law. *See also* 40 C.F.R. § 1506.1(a) ("no action concerning the [agency's] proposal shall be taken which would . . . [h]ave an

adverse environmental impact" or "[l]imit the choice of reasonable alternatives").[12]

II. TO OBTAIN RELIEF FOR A NEPA VIOLATION AFFECTING A WILDLIFE OR PLANT SPECIES, PLAINTIFFS NEED NOT DEMONSTRATE SPECIES-LEVEL HARM.

In arguing that respondents were not entitled to the specific injunctive relief granted by the district court, petitioners (echoed by the government, Gov't Br. at 28) proffer an extreme position regarding the irreparable injury standard in this case, arguing that respondents must show "species-level harm" to conventional and organic alfalfa before an injunction may issue; in advancing that argument, petitioners purportedly borrow the applicable standard from the irreparable injury standard in the context of an affected wildlife species. Pet. Br. at 36-37. As

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[12] The petitioners' and government's contention that the lower courts should have deferred to USDA's proposed interim measures is also impossible to reconcile with NEPA's design. *See* Gov't Br. at 39-42. Not only are courts under no obligation to defer to an agency's post-hoc rationalizations in any APA case, *see* Resp. Br. at 47 – let alone one in which the agency has already been found to have violated federal law – but the entire premise behind the EIS requirement is that, without that document, the agency itself lacks information essential to informed decisionmaking *See Pub Citizen*, 541 U.S. at 769. Indeed, for a court to simply rubber-stamp measures that the agency may prefer but have not been afforded the requisite "hard look" in an EIS, *Baltimore Gas and Elec. Co.*, 462 U.S. at 100, would be to compound, rather than rectify, the NEPA violation.

respondents point out, this argument was not advanced below and hence should be deemed waived. Resp. Br. at 38-39. But if the Court nevertheless addresses the argument, any notion that irreparable injury to a NEPA plaintiff's interests in a wildlife or plant species may *only* be established by demonstrating species-level harm is impossible to reconcile with this Court's own precedents, lower court rulings applying NEPA, and the statute itself.

To begin with, it is now well-established that the "desire to use or observe an animals species, even for purely esthetic purposes, is undeniably a cognizable interest for purposes" of both injury in fact and irreparable injury analysis. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 562 (1992). This Court has further held that a "person who *observes or works with a particular animal* threatened by a federal decision is facing perceptible harm, since the subject of his interest will no longer exist." *Id.* at 566. Plainly, a plaintiff's interest in "us[ing] or observ[ing] an animal species" (or plant species) or in "observ[ing] or work[ing] with a particular animal" (or plant) may be gravely impaired through *adverse impacts on wildlife or plants in a specific location frequented by the individual* regardless of whether the species as a whole will be driven to extinction by the action under review.

Indeed, this Court evidently recognized the potential for precisely such injury in *Winter*. Thus, although the Navy asserted that the plaintiffs in that case needed to show species-level harm in order to

demonstrate irreparable injury to their interests in observing and enjoying marine mammals off the coast of Southern California, 129 S. Ct. at 375, the Court's ruling did *not* endorse that argument. Rather, in view of declarations from the plaintiffs and their members that they routinely observed and studied whales and other marine mammals in specific locations where the training exercises were occurring, and that their ability to engage in those localized activities would be irreparably injured by the Navy's use of sonar *regardless* of whether entire species would be wiped out, the Court found that the plaintiffs *had* indeed asserted "serious[ ]" and "legitimate[ ]" injuries due to *their* diminished opportunities to view, photograph, enjoy, and research members of the affected species in particular geographical areas used by the plaintiffs. *Id.* at 377-78. The Court simply held that those acknowledged interests were *outweighed* by overriding national security interests. *Id.* at 378 (concluding that "the balance of equities and consideration of the overall public interest in this case [protecting national security] tip strongly in favor of the Navy").

The Court's recognition in *Winter* that those whose ability to enjoy or benefit from a species in a *particular geographical area* will be impaired by a federal action do indeed have "serious" interests that may support relief in a NEPA case is consistent with the Court's pronouncement as to who has standing to seek such relief. In *Lujan*, the Court observed that "under our case law, one living adjacent to the site for

proposed construction of a federally licensed dam has standing to challenge the licensing agency's failure to prepare an environmental impact statement." 504 U.S. at 572 n. 7.

Thus, expanding on the Court's paradigmatic example, those "living adjacent" to the proposed dam site would certainly have standing to argue, among other issues, that an EIS should be prepared because the dam would destroy a river that had long been used by local residents to fish for trout. Yet, under petitioners' approach to the irreparable injury analysis, although the nearby residents "would obviously be concretely affected" by this localized wildlife impact, *id.* at n. 8, and hence would have standing to *bring* a NEPA case, they could not rely on that same impact to argue that the dam should be halted pending completion of a required EIS unless they could show that the dam would cause the extinction of trout everywhere. That argument makes no sense. *Cf. Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 183 (2000) (individuals who refrained from using a nearby river because of pollution concerns were "persons 'for whom the aesthetic and recreational values of the area will be lessened' by the challenged activity" regardless of whether they could go to other rivers) (citation omitted); *Japan Whaling Ass'n v. Am. Cetacean Soc'y*, 478 U.S. 221, 230 n. 4 (1986) (conservation organizations "undoubtedly have alleged a sufficient 'injury in fact' in that the whale

watching and studying *of their members* will be adversely affected by continued whale harvesting") (emphasis added).

The argument makes even less sense when NEPA's specific requirements are considered. As respondents point out, Resp. Br. at 32, and as the example in *Lujan* illustrates, a federal action's environmental impacts may be deemed significant, and hence require an EIS, *solely* because it has locally or regionally significant effects on the human environment. *See* 40 C.F.R. § 1508.27(a). Congress further emphasized the importance of analyzing environmental impacts on a local scale, requiring agencies completing an EIS to consider "the relationship between *local short-term uses* of man's environment and the maintenance and enhancement of long-term productivity." 42 U.S.C. § 4332(C)(iv) (emphasis added).

Hence, it is indisputable – and petitioners surely do not deny here – that an agency action can necessitate preparation of an EIS because it has a regionally or locally significant effect on a wildlife or plant species, and thus a serious adverse impact on the ability of regional or local residents to use or enjoy that species, even if the action does not cause the extinction of an entire species. *E.g.*, *Anderson v. Evans*, 371 F.3d 475, 490 (9th Cir. 2004) ("Even if the eastern Pacific gray whales overall . . . are not significantly impacted by the Makah Tribe's whaling, the summer whale population in the *local* Washington area may be significantly affected. Such local effects are a

basis for a finding that there will be a significant impact from the Tribe's hunts.") (citing 40 C.F.R. § 1508.27(a)); *Fund for Animals v. Norton*, 281 F. Supp. 2d 209, 232-34 (D.D.C. 2003) ("[T]he impact of a proposed action on a local population of a species, even where all parties acknowledge that the action will have little or no effect on broader populations, is a basis for a finding that there will be a significant impact" that should be studied in an EIS (quotation omitted)). It surely cannot be the law that a level of environmental injury that is significant enough to trigger the EIS requirement – as is the case for locally or regionally significant wildlife impacts – is, at the same time, legally incapable of supporting injunctive relief while the EIS is being prepared.

Indeed, petitioners' demand for such species-level impacts is not only difficult to harmonize with this Court's precedents and with NEPA itself, but it has been squarely rejected by the vast majority of lower courts that have considered the issue and have correctly reasoned that the *plaintiffs'* aesthetic, recreational, research, or other interests may be impaired by regional or local impacts on wildlife resources. *E.g.*, *Greater Yellowstone Coal.*, 321 F.3d at 1261 (finding that threats to the "primary breeding area for bald eagles in the Greater Yellowstone area" qualified as irreparable injury to plaintiffs' interests under NEPA even if plaintiffs did not "establish harm to the species as a whole"); *Fund for Animals v. Clark*, 27

F. Supp. 2d 8, 14 (D.D.C. 1998) (the combination of the injury suffered by plaintiffs due to federal defendants' procedural failure to comply with NEPA and "the aesthetic injury the individual plaintiffs would suffer from seeing" bison being killed in a federally authorized hunt met plaintiffs' "burden of demonstrating the presence of an irreparable harm").[13]

Likewise, under NEPA and other federal environmental statutes, courts have long found irreparable injury where the plaintiffs' concrete interests in a particular forest are adversely affected by agency action – irrespective of whether the action at issue would entirely eliminate all forests or the affected tree species. *E.g.*, *Sierra Club v. Bosworth*, 510 F.3d 1016, 1034 (9th Cir. 2007) (finding irreparable injury where trees in certain forests would be logged or burned in violation of NEPA); *Idaho Sporting Cong. v. Rittenhouse*, 305 F.3d 957, 974 (9th Cir. 2002) (enjoining two timber sales after finding irreparable injury to plaintiffs if old-growth forests were cut); *Buckeye Forest Council v. U.S. Forest Serv.*, 337

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[13] *See also Ala. Wildlife Alliance v. Jensen*, 108 F.3d 1065, 1068 (9th Cir. 1997) (plaintiffs challenging an agency decision to allow commercial fishing in Glacier Bay National Park suffered serious "aesthetic and recreational harm" by seeing "sea lions in the bay with huge trolling lures hanging from their mouths"); *Humane Soc'y of the United States v. Hodel*, 840 F.2d 45, 52 (D.C. Cir. 1988) (organizations' members were injured by federal actions that resulted in their witnessing "animal corpses and environmental degradation" at federal wildlife refuges).

F. Supp. 2d 1030, 1039 (S.D. Ohio 2004) (preliminarily enjoining the Forest Service from "tree cutting, thinning, logging, and prescribed burning" because of the irreparable harm that would result to the plaintiffs' interests). Once again, these rulings correctly recognize that plaintiffs in NEPA cases may be irreparably harmed by injury to the localized environment in which the plaintiffs have a concrete interest, regardless of whether they are able to demonstrate a "species-level harm" from an agency's failure to comply with NEPA. Pet. Br. at 36-37.

Indeed, petitioners cite to a single NEPA case in support of their position that species-level harm must be shown to demonstrate irreparable injury in a wildlife context. Pet. Br. at 36. However, in that case, *Fund for Animals v. Frizzell*, 530 F.2d 982 (D.C. Cir. 1975), the court not only found that an EIS was *not* required with regard to the action at issue, *id.* at 988 n. 15, but the court did not even address the question of whether a local or regional impact on wildlife could be sufficient to support an injunction because no such argument was made. Accordingly, the ruling has been distinguished by other courts which *have* addressed that specific question, and have found that such an impact may be sufficient to maintain the *status quo*

pending compliance with NEPA. *See Greater Yellowstone Coal.*, 321 F.3d at 1256-57.[14]

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[14] The only other case cited by petitioners (or the government) – *Water Keeper Alliance v. Dep't of Defense*, 271 F.3d 21 (1st Cir. 2001) – is even less apposite. *Water Keeper Alliance* did not involve a NEPA claim but, rather, an *unsuccessful* challenge under section 7 of the ESA, which requires federal agencies to consult with the Fish and Wildlife Service regarding the impacts of their activities on listed species. *Id.* at 25; *see* 16 U.S.C. § 1536(a)(2). In reviewing a district court's refusal to issue a preliminary injunction based on an asserted procedural violation of that provision, the First Circuit first found that the plaintiffs were "unlikely to succeed on the merits" of their claim that the Navy had failed to adequately solicit the expert agency's views on the impacts of training exercises on listed species. *Water Keeper Alliance*, 271 F.3d at 31-33. Thus, while recognizing that the "ESA restricts the equity power of the court as to findings of irreparable injury," *id.* at 33 (citing *Tenn. Valley Auth. v. Hill*, 437 U.S. 153); *see also Oakland Cannabis Buyers' Coop.*, 532 U.S. at 496-98, and clearly suggesting that a proven violation of the section 7 process could *alone* have been sufficient to warrant injunctive relief in view of *Hill*, 271 F.3d at 33, the court reasoned that, *in the absence of any violation* of the ESA's procedural or substantive mandates, the plaintiffs could not support such relief without making some "concrete showing" of how the action "may affect the species" in ways the consultation had not addressed. *Id.* Accordingly, while there is no reason for the Court to address ESA precedents in resolving this case, nothing in *Water Keeper Alliance* supports the notion that a species-level impact is necessary to support injunctive relief in every legal context; indeed, the ruling does not even discuss, let alone reject, the proposition that regional or local impacts on wildlife or plant species may be sufficient to support such relief in appropriate cases.

CONCLUSION

For the foregoing reasons, the Court should reject petitioners' challenges to the ruling below.

Respectfully submitted,

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No. 09-475

In The Supreme Court of the United States

MONSANTO COMPANY, ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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INTEREST OF THE *AMICI CURIAE*[1]

Amici curiae are a national environmental organization and eight law professors. The Natural Resources Defense Council, which has 1.2 million members and supporters, uses law and science to secure a safe and healthy environment for all living things. The *amici* law professors are teachers and students of environmental law, and have a long-standing interest in how the principles of equitable relief are applied in environmental cases.

The *amici* believe this is a case where respondents have readily met the traditional "likelihood of irreparable injury" requirement. The district court and court of appeals both expressly applied that test and found that irreparable injury was likely to occur. No good cause exists for this Court to revisit that factbound ruling. Petitioners, however, seek in their brief to inject a new legal issue, not raised below, by suggesting that the "likelihood" standard requires a rigid application of a "more likely than not" test for the probability of harm, irrespective of its potential magnitude. This case does not provide the appropriate vehicle to consider the validity of this

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[1] The Government's written consent to the filing of this brief is on file with the Clerk of this Court. The other parties' written consents are being submitted with this brief. Pursuant to S. Ct. R. 37.6, *amici* affirm that this brief was not authored in whole or in part by counsel for a party, and that no monetary contribution to the preparation or submission of this brief was made by any person other than *amici* or their counsel.

newly-proffered test, not passed on by the courts below. In any event, the proposed standard is without merit. Should the Court decide to address the issue, it should therefore squarely reject the proffered standard. The sole purpose of this *amicus* submission is to address this issue in case the Court decides to consider it.

A further description of the *amici* is set forth in an Appendix to this brief.

SUMMARY OF THE ARGUMENT

It is hornbook law that courts may issue injunctions only where there is a likelihood of irreparable injury. *See, e.g., Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 375 (2008) (*dicta*), and *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983) (requiring a "sufficient likelihood" of such injury). Monsanto Co. ("Monsanto") argues that this formulation denies courts the power to issue injunctions in response to threatened harms, no matter how serious their potential consequences, unless those harms are more than 50% likely to materialize. Brief for Monsanto ("Petr.'s Br.") 33, 41-47. This argument wrongly assumes that the term "likelihood" connotes "more likely than not" in this context. It also ignores the basic principle that whether a threatened harm is "sufficiently likely" turns on both the *probability* of its occurrence and the *severity* of its consequences should it occur.

Monsanto's reading of the traditional equitable test is both illogical and ahistorical. Under its approach, for example, courts would be unable to enjoin the maintenance of severe fire hazards in residential areas if the risks of conflagration were "only" 40%. Similarly, a court would be powerless even where a simple injunctive order might be all that is required to preclude a 50% chance that a lethal virus would be introduced to New York City's water supply.

As will be shown below, the courts of equity long have used both public and private nuisance principles to halt conduct and address conditions posing serious threats to the public weal, regardless of whether the feared harm was more likely than not to come to fruition. While at first there were not many cases, their numbers have increased over the years. Where the threats have been sufficiently serious, the courts have simply deemed the circumstances giving rise to them to be nuisances, which in turn has enabled them to issue injunctive relief where necessary to achieve equity. In case after case, the courts have applied these dynamics without requiring that the harm be preponderantly likely to occur. In effect, where faced with sufficiently serious threats of irreparable harm, courts have recognized that the threats themselves constitute a likely and enjoinable injury, under bedrock principles of equity jurisdiction.

That courts show an increasing tendency to focus on the overall significance of the relevant threats, rather than solely on the likelihood that the feared

consequences will come to pass, is fully consistent with the Restatement (Second) of Torts. It also comports with both modern principles of risk assessment and the analysis that this Court and others have applied in related contexts. And finally, it closely tracks an analogous development in environmental law, the advent of the so-called "imminent hazard" provisions that Congress patterned on public nuisance principles.

In the face of this longstanding history and legal evolution, Monsanto reads this Court's opinion in *Winter* as mandating a significant reworking of the basic principles of equitable jurisdiction. Petr.'s Br. 41-47. *Winter*, however, is far too slender a reed to support such a major change. Indeed, *Winter* not only fails to signal any such change, it expressly embraces traditional principles. Moreover, it contains no holding at all regarding the irreparable injury requirement.

We of course recognize that judicial enforcement of the statute at issue in this case, the National Environmental Policy Act, 42 U.S.C. § 4321, *et seq.* ("NEPA"), focuses on the procedures it prescribes. This does not mean, however, that this Court should discount its congressionally-articulated substantive goals when considering the presence of irreparable injury. Congress intended for NEPA to influence governmental decision-making profoundly. To effectuate this goal, Congress required agencies to undertake extensive analysis whenever their actions may "significantly affect" the environment, *see* 42 U.S.C.

§ 4332(2)(C) and 40 C.F.R. § 1501.4. That the potential for such effects was intended to trigger action only serves to emphasize why the "likelihood of irreparable injury" requirement should not be deemed to require a more-likely-than-not standard. This Court should honor Congress's intent that potentially significant environmental risks be examined by ensuring that federal courts have the broad equitable discretion to determine, in appropriate cases, that an agency's failure to comply with NEPA poses a sufficient threat of harm to constitute a likelihood of irreparable injury, even if that harm is not preponderantly likely to occur.

ARGUMENT

I. THE COURTS OF EQUITY LONG HAVE HAD THE AUTHORITY TO ISSUE INJUNCTIONS IN THE FACE OF SIGNIFICANT THREATS.

a. The history of the common law fully supports the idea that courts may address situations that pose unreasonable harm of injury, and that they may issue injunctions in response to those threats.

Under the common law, courts long have had the power to issue injunctions in the face of significant threats, regardless of whether the threatened harms were at least 51% likely to come to fruition. In these

cases, all plaintiffs have been required to show is that the conduct poses a significant threat to the public health, safety, or welfare. They have not been required to show a preponderant likelihood that the threat will result in the feared consequences. The circumstances themselves, if sufficiently threatening, constitute a nuisance and give rise to a claim for injunctive relief.

This power may be most apparent in the realm of public nuisance law. This Court traced the history of the equitable power to address these nuisances in *Mugler v. State of Kansas*, 123 U.S. 623 (1887):

> "In regard to public nuisances," Mr. Justice Story says, "the jurisdiction of courts of equity seems to be of very ancient date, and has been distinctly traced back to the reign of Queen Elizabeth. The jurisdiction is applicable, not only to public nuisances, strictly so called, but also to purprestures upon public rights and properties. . . . In case of public nuisances, properly so called, an indictment lies to abate them, and to punish the offenders. But an information also lies in equity to redress the grievance by way of injunction." 2 Story, Eq. Jur. §§ 921, 922. The ground of this jurisdiction in cases on purpresture, as well as of public nuisances, is the ability of courts of equity to give a more speedy, effectual, and permanent remedy than can be had at law. They can not only prevent nuisances that are threatened, and before irreparable mischief ensues, but arrest or abate those in progress, and, by

> perpetual injunction, protect the public against them in the future; whereas courts of law can only reach existing nuisances, leaving future acts to be the subject of new prosecutions or proceedings. *This is salutary jurisdiction, especially where a nuisance affects the health, morals or safety of the community. Though not frequently exercised, the power undoubtedly exists in courts of equity to protect the public against injury.* [Citations omitted].

Id. at 672-73 (emphasis added); *see also United Steelworkers of Am. v. United States*, 361 U.S. 39, 60 (1959) (citing English public nuisance cases involving injunctions as far back as 1587). Additionally, this Court long has recognized that public nuisance doctrine embraces both health and other environmental protection concerns. *Georgia v. Tenn. Copper Co.*, 206 U.S. 230 (1907) (deeming air pollution a public nuisance because of its impacts on both forests and public health in a neighboring state); *see also Ariz. Copper Co. v. Gillespie*, 230 U.S. 46, 56-57 (1913) (water pollution deemed a public nuisance), and *New Jersey v. City of New York*, 283 U.S. 473 (1931) (same).

In most nuisance cases, both public and private, the relevant conduct or conditions already have given rise to harm, and thus it is often easy for courts to find a sufficient threat of future harm. That was certainly true in *Tennessee Copper*, *Arizona Copper*, and *City of New York*. In other cases, however, the threat is present but has not yet given rise to harm.

Where the courts have deemed such threats sufficiently serious, however, they have not hesitated to find that the conduct or condition constitutes a nuisance, without inquiring into whether the threatened harms were more likely than not to materialize. As early as 1799, for example, upon finding that certain houses in which the defendant was storing sugar were structurally unsound, the chancellor in *London v. Bolt*, 5 Ves. Jun. 129, 31 Eng. Rep. 507 (Ch. 1799), relied on public nuisance doctrine to issue an injunction preventing the defendant from adding any additional sugar. Similarly, in *R. v. Vantandillo*, 4 M. & S. 73, 105 Eng. Rep. 762 (K.B. 1815), the court determined that carrying a child with smallpox along a public highway constituted a public nuisance, without any finding regarding the likelihood that this conduct would cause harm to anyone else.[2]

In this country, the earliest cases recognizing that a significant risk could in itself constitute a nuisance arose in the context of private nuisance law. In *Tyner v. People's Gas Co.*, 132 Ind. 408, 31 N.E. 61 (1892), for example, the Indiana Supreme Court overruled a demurrer where the defendant was intending to use nitroglycerin to "shoot" a well on its property,

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[2] This was a criminal case brought in the King's Bench, a court which in 1815 could not grant injunctions. We cite it here as an example of another early decision deeming conduct threatening to the public weal to constitute a public nuisance, without either quantifying the risk or concluding that the threatened harm was likely to materialize.

which the plaintiff alleged would pose a serious, but unquantified, risk of explosion, thus endangering both the plaintiff and his family. The court stated that:

> It is settled by our own decisions that the erection or the maintaining of anything that is injurious to health . . . , so as essentially to interfere with the comfortable enjoyment of life or property, constitutes a private nuisance. To live in constant apprehension of death from the explosion of nitroglycerin is certainly an interference with the comfortable enjoyment of life. Injunction is 'the proper remedy for an injury of this kind.

31 N.E. at 62. Similarly, in *Ferry v. City of Seattle*, 116 Wash. 648, 303 P. 40 (1922), the Washington Supreme Court affirmed a lower court injunction prohibiting the construction of a dam where it would pose an unacceptable risk to neighboring property owners. Here also, neither the plaintiff nor the court quantified the risk. In its analysis, though, the court explicitly factored in the magnitude of the consequences when discussing their probability:

> The test as to whether a structure of the proposed character is to be declared a nuisance turns on whether the complaining property owners are under a reasonable apprehension of danger, and the question of the reasonableness of the apprehension turns again, not only on the probable breaking of the reservoir, but the realization

> of the extent of the injury which would certainly ensue; that is to say the court will look to consequences in determining whether the fear existing is reasonable. For instance, if the reservoir were being built in some place where, should it break, the resultant damage would be merely to property which could adequately be recompensed, the court would be more apt to hesitate in declaring it a nuisance than where, should a break occur, not only property of immense value would be destroyed, but many lives would be lost as well.

Id. at 662.

Early treatises also recognized the need to apply a sliding scale regarding the likelihood of the harm in situations in which the consequences may be severe. As early as in 1919, Pomeroy's Treatise on Equitable Remedies provided that:

> . . . On the one hand, a mere possibility of a future nuisance will not support an injunction; it must be probable. On the other hand, the plaintiff . . . does not need to establish this probability by proof amounting to a virtual certainty that the nuisance will occur, nor even proof which establishes it beyond a reasonable doubt; *it is sufficient if he show that the risk of its happening is greater than a reasonable man would incur. And the balance between these two rules will be affected by the seriousness of the nuisance feared, the strength required for the plaintiff's proof diminishing somewhat as*

> *the greatness of the apprehended damage increases.*

Pomeroy, A Treatise on Equity Jurisprudence and Equitable Remedies, Vol. 5, § 523, p. 4398 (1919) (emphasis added).

By the middle of the 20th century, courts were applying this logic in the public nuisance context. In *Harris Stanley Coal & Land Co. v. Chesapeake & Ohio Railway Co.*, 154 F.2d 450 (6th Cir. 1946), *cert. denied*, 329 U.S. 761 (1946), a railroad appealed the district court's denial of an injunction through which the railroad sought to preclude a mining company from removing pillars of coal that were designed to support the surface of the land. *Id.* at 452. The lower court had found that there was a "possibility or even probability that the mountain side would slip or subside," but nonetheless denied the injunction. *Id.* The Sixth Circuit reversed, emphasizing the seriousness of the potential consequences:

> If the threatened injury to the railroad right-of-way be envisioned merely as the sliding of some of the surface material of the mountain upon the railroad right-of-way necessitating some expense in its removal and in the repair of the roadbed, we might well say that recovery of damages in a suit at law provides adequate remedy. We have here, however, a railroad over which pass trains bearing passengers and freight. Their daily number is not disclosed by the record, and being but a branch line it may be assumed that the traffic is not heavy. Nevertheless, traffic

> there is, and the effect of a substantial mountain slide upon a passing train might well be catastrophic. It may be that such disaster could occur only upon a concatenation of circumstances of not too great probability, and that the odds are against it. It is common experience, however, that catastrophies occur at unexpected times and in unforeseen places. . . . A court of equity will not gamble with human life, at whatever odds, and for loss of life there is no remedy at law.

Id. at 453. *See also County of San Diego v. C. W. Carlstrom*, 196 Cal. App. 2d 485, 16 Cal. Rptr. 667 (1961) (finding a fire hazard to be a public nuisance without any quantification regarding the likelihood of a fire).

More recently, the courts have applied this kind of risk-based logic in a broader array of equitable contexts, finding nuisances and authorizing injunctive relief in situations where it has been far from certain that the relevant threat, while significant, was likely to give rise to the feared consequences. Perhaps most tellingly, this Court in *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003 (1992), implicitly assumed that risk analysis can play a role in determining what constitutes a nuisance. There, in exploring the relationship between takings law and nuisance principles, the Court insisted that "the corporate owner of a nuclear generating plant" could not successfully raise a takings claim "when it is directed to remove all improvements from its land

upon discovery that the plant sits astride an earthquake fault." *Id.* at 1029. The mere existence of a fault in such a situation would not, of course, make an earthquake more likely than not, let alone create a likelihood of radioactive release. As the Court appeared to recognize, it is the severity of the potential consequences that would make the threat abatable as a public or private nuisance, and hence undermine a takings claim.

Other courts have applied a similar calculus to nuisance cases involving hazardous waste contamination[3] and threats to the public safety from the possibility of gang violence,[4] over-aggressive protesters,[5]

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[3] *See, e.g., Village of Wilsonville v. SCA Servs., Inc.*, 77 Ill. App. 3d 618, 635-636, 396 N.E.2d 552, 564 (4th Dist. 1979), *aff'd*, 86 Ill. 2d 1, 426 N.E.2d 824 (1981) ("The trial court could have determined from the evidence that the harm that would impend because of the danger that hazardous substances might escape was so serious that no justification existed to deny the injunction even though the feared harm was uncertain as to occurrence and, in any event, unlikely to occur until the distant future"); *Wood v. Picillo*, 443 A.2d 1244, 1247 (1982) ("According to experts, the chemicals present on defendant's property and in the marsh, left unchecked, would eventually threaten wildlife and humans well downstream from the dump site.").

[4] *People ex rel. Gallo v. Acuna*, 14 Cal.4th 1090, 929 P.2d 596, 60 Cal. Rptr. 2d 277 (1997).

[5] *See N.Y. State Nat'l Org. for Women v. Terry*, 886 F.2d 1339, 1362 (2d Cir.), *cert. denied*, 495 U.S 1339 (1989) ("We have no doubt that-absent the requested relief-the health and security of a considerable number of persons was and would be endangered by the demonstrations. Accordingly, the district court correctly found that defendants' activities constituted a public nuisance, and properly granted the City summary

(Continued on following page)

and potentially violent demonstrations.[6] In none of these cases did the courts feel the need to quantify the likelihood that the threatened harms would come to pass. After identifying a significant threat to the public weal, they simply found nuisances to exist and issued injunctions designed to abate them.

b. The Restatement (Second) of Torts is fully in accord with these cases.

The Restatement (Second) of Torts ("Restatement") expressly contemplates that conduct and conditions giving rise to unreasonable risks of harm are actionable under principles of both public and private nuisance. It further contemplates that courts may enjoin these injuries without first finding a preponderant likelihood that the relevant harm will materialize.

Turning first to public nuisances, the Restatement defines such a nuisance as "an unreasonable interference with a right common to the general public." Restatement (Second) of Torts § 821B (1977).

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judgment on this claim."); *Hirsh v. City of Atlanta*, 261 Ga. 22, 401 S.E.2d 530 (1991).

[6] *Wilkinson v. Forst*, 832 F.2d 1330 (2d Cir. 1987), *cert. denied sub nom Kelly v. Wilkinson*, 485 U.S. 1034 (1988) (authorizing magnetometer searches); *but see Christian Knights of the Ku Klux Klan Invisible Empire, Inc. v. Dist. of Columbia*, 972 F.2d 365 (D.C. Cir. 1992) (identifying First Amendment constraints that might limit injunctions such as those allowed to stand in *Wilkinson*).

It further provides that "[c]ircumstances that may sustain a holding that an interference with a public right is unreasonable include [situations in which] the conduct involves a significant interference with the public health, the public safety, the public peace, the public comfort or the public convenience." *Id.* Comment b to that section lists "the maintenance of a pond breeding malarial mosquitoes" as an example of an interference with the public health, and "bad odors, dust and smoke" as examples of interferences with the public comfort. *Id.* § 821B, cmt. b, p. 88. Elsewhere, the Restatement cites pollution leading to a beach closure as yet another example of a public nuisance. *Id.* § 832, cmt. b, p. 143.

Under the Restatement, an "unreasonable" or "significant" interference with the public health, safety, peace, comfort, or convenience is all that is required. Nothing in the Restatement suggests that public-nuisance plaintiffs must show a preponderant likelihood that someone will actually get sick or suffer a physical injury or some other clear manifestation of harm, either as part of their prima facie case or to establish an entitlement to equitable relief. In the beach closure context, for example, it is presumed that a health threat warranting beach closure is actionable, without any required showing that would-be swimmers face at least a 51% likelihood of becoming ill.

The provisions of the Restatement pertaining to private nuisances apply similar logic. Section 821D defines a private nuisance as a "nontrespassory

invasion of another's interest in the private use or enjoyment of land." *Id.* § 821D. Sections 821F and 822 note that the harm must be both "significant" and either "intentional and unreasonable" or "unintentional and otherwise actionable" under either negligence standards or principles of strict liability. *Id.* §§ 821F and 822, respectively.[7]

It is in the Comments to § 822 that the Restatement makes clear that a significant risk of harm constitutes a cognizable injury under this formulation. Comment g, addressing the unreasonableness requirement in the context of intentional invasions, provides that:

> . . . The very existence of organized society depends upon the principle of "give and take, live and let live," and therefore the law of torts does not attempt to impose liability or shift the loss in every case in which one person's conduct has some detrimental effect on another. Liability for damages[8] is imposed

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[7] A comment to the former provision indicates that "significant" means "harm of importance, involving more than slight inconvenience or petty annoyance." Restatement, *supra*, § 821F, cmt. c, p. 105.

[8] Although this provision speaks explicitly only to liability for damages, the Restatement makes clear that injunctive relief is available in appropriate cases for private nuisances. *See*, *infra*, pp. 18-19. It is perhaps for this reason that the authors of Prosser and Keaton on Torts edited out the words "for damages" when they quoted this passage in their treatise. Prosser and Keaton on Torts, 5th Ed., p 629 (1984).

> in those cases in which the harm *or risk* to one is greater than he ought to be required to bear under the circumstances, at least without compensation.[9]

Id. § 822, cmt. g, p. 112 (emphasis added).

Chapter 48 of the Restatement, which deals specifically with the appropriateness of tort-related injunctions, further illuminates the role that risk plays in both public and private nuisance doctrine. First, § 933(1) indicates that injunctions are available for both committed and threatened torts, depending upon the appropriateness of such issuance as determined by the factors listed in § 936. *Id.* § 933(1). In turn, § 936(1) contemplates a "comparative appraisal of all of the factors in the case," including:

> (a) the nature of the interest to be protected,
>
> (b) the relative adequacy to the plaintiff of injunction and other remedies,
>
> (c) any unreasonable delay by the plaintiff in bringing suit,
>
> (d) any related misconduct on the part of the plaintiff,

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[9] Comment k, dealing with unintentional invasions, also focuses on risk. Because that note addresses liability based on negligence theories, however, it emphasizes that "it is the risk of harm that makes the conduct unreasonable." Restatement, *supra*, § 822, cmt. k, p. 114.

> (e) the relative hardship likely to result to defendant if an injunction is granted and to plaintiff if it is denied,
>
> (f) the interests of third persons and of the public, and
>
> (g) the practicability of framing or enforcing the order or judgment.

Id. § 936(1).

In Comment b to Section 933, the Restatement more thoroughly addresses the need to enjoin improbable but serious harms, when it discusses "threatened torts." There, it speaks in the following terms:

> The expression "threatened tort," as used in Subsection (1) of this Section, contemplates, as a condition for the grant of an injunction, a threat of sufficient seriousness and imminence to justify coercive relief. The seriousness and imminence of the threat are in a sense independent of each other, since a serious harm may be only remotely likely to materialize and a trivial harm may be quite imminent. Yet the two elements must be considered together in the decision of any given case. *The more serious the impending harm, the less justification there is for taking the chances that are involved in pronouncing the harm too remote.*

Id. § 933, cmt. b, p. 561 (emphasis added). A comment to § 821F both emphasizes this point and makes it

specifically applicable to both public and private nuisances:

> . . . [E]ither a public or private nuisance may be enjoined because harm is threatened that would be significant if it occurred, and that would make the nuisance actionable under the rule here stated, although no harm has yet resulted.

Id. § 821F, cmt. b, p. 105.

In short, the Restatement contemplates that the significance of the risk can be considered in determining both whether a nuisance exists and whether injunctive relief is an appropriate remedy. In neither context is it necessary that there be a preponderant likelihood that the threatened harm will come to pass; if the potential harm is particularly serious, the Restatement contemplates that courts will be prepared to guard against even a low likelihood of its occurring.

Finally, once a nuisance has been established, the Restatement does not require a separate showing regarding the likelihood of irreparable injury. Section 936(1) includes the other traditional equitable factors, but not that one. Although this goes unexplained in the Restatement, the only logical conclusion is that the nuisance finding equates to a finding that there is a sufficient likelihood of irreparable

injury.[10] This interpretation draws support from § 7 of the Restatement, which distinguishes the concept of "injury" from that of "harm." The word "injury," it makes clear, denotes "the invasion of any legally protected interest of another," as distinct from "harm," which is used to mean an actual loss or detriment. *Id.* § 7 (1965). Thus, under the Restatement one can be irreparably injured without having actually been harmed.

c. The tendency of courts to issue injunctions in the face of significant threats comports with sound risk analysis and the approaches that this Court and others have taken in analogous contexts.

If there is one unifying principle in the modern regulatory world, it is that analyzing risk requires an understanding not only of the likelihood of a particular outcome, but also of the severity of its potential effects. Nat'l Research Council, Science and Judgment in Risk Assessment 4 (1994); *School Bd. of*

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[10] The only reference to anything like an irreparable harm requirement is in Comment b, which includes a statement that:

> . . Other factors, not here listed, may be considered, as for example, that of the sufficiency of the seriousness and imminence of the threat of tort, discussed in § 933(1), Comment b.

Restatement, *supra*, § 936(1), cmt. b, p.567. This of course, though, merely replicates the analysis necessary in the first place to determine whether there is a qualifying tort.

Nassau County, Fla. v. Arline, 480 U.S. 273, 287-88 (1987) ("*Arline*").

Ever since Judge Hand first analyzed negligence issues in terms of whether the burden of the relevant precautions was less than the probability of an accident, multiplied by the gravity of the resulting injury, *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947), courts have increasingly embraced modern risk analysis. This Court expressly embraced the fundamental principles of risk assessment in *Arline*. As the Court later summarized in *Bragdon v. Abbott*, 524 U.S. 624 (1998), *Arline* dealt with the

> . . . importance of prohibiting discrimination against individuals with disabilities while protecting others from significant health and safety risks, resulting, for instance, from a contagious disease. In *Arline*, the Court reconciled these objectives by construing the [relevant statute] not to require the hiring of a person who posed a significant risk of communicating an infectious disease to others.

Id. at 649 (quotation omitted). In *Arline*, the Court determined that the "significance" inquiry should include:

> "[findings of] facts, based on reasonable medical judgments given the state of medical knowledge, about (a) the nature of the risk (how the disease is transmitted), (b) the duration of the risk (how long is the carrier infectious), (c) the severity of the risk (what

> is the potential harm to third parties) and (d) the probabilities the disease will be transmitted and will cause varying degrees of harm."

Arline, 480 U.S. at 288 (quoting from a brief filed by the American Medical Association).

This Court also squarely embraced a "significant threats" approach in *Helling v. McKinney*, 509 U.S. 25 (1993). There, the Court determined that the Eighth Amendment's "cruel and unusual punishment" standard forbids not only prison conditions that are likely to make a particular inmate ill, but also those that pose "an unreasonable risk of serious damage to [a prisoner's] future health." *Id.* at 35.

The lower courts have applied similar logic in related contexts. Most significantly, they have adopted risk-based ideas in applying the "likelihood of prevailing on the merits" standard that governs the issuance of preliminary injunctions. In *American Hospital Supply Corp. v. Hospital Products Ltd.*, 780 F.2d 589 (7th Cir. 1986), for example, Judge Posner wrote that:

> A district judge asked to decide whether to grant or deny a preliminary injunction must choose the course of action that will minimize the costs of being mistaken. Because he is forced to act on an incomplete record, the danger of a mistake is substantial. And a mistake can be costly. If the judge grants the preliminary injunction to a plaintiff who it later turns out is not entitled to any judicial

relief – whose legal rights have not been violated – the judge commits a mistake whose gravity is measured by the irreparable harm, if any, that the injunction causes to the defendant while it is in effect. If the judge denies the preliminary injunction to a plaintiff who it later turns out is entitled to judicial relief, the judge commits a mistake whose gravity is measured by the irreparable harm, if any, that the denial of the preliminary injunction does to the plaintiff.

These mistakes can be compared, and the one likely to be less costly can be selected, with the help of a simple formula: grant the preliminary injunction if but only if $P \times H_p > (1 - P) \times H_d$, or, in words, only if the harm to the plaintiff if the injunction is denied, multiplied by the probability that the denial would be an error (that the plaintiff, in other words, will win at trial), exceeds the harm to the defendant if the injunction is granted, multiplied by the probability that granting the injunction would be an error. That probability is simply one minus the probability that the plaintiff will win at trial; for if the plaintiff has, say, a 40 percent chance of winning, the defendant must have a 60 percent chance of winning (1.00 – .40 = .60). The left-hand side of the formula is simply the probability of an erroneous denial weighted by the cost of denial to the plaintiff, and the right-hand side simply the probability of an erroneous grant weighted by the cost of grant to the defendant.

Id. at 593; *see also FoodCom Int'l v. Barry*, 328 F.3d 300, 303 (7th Cir. 2003). Similarly, the Second Circuit has applied a sliding-scale approach in the same context, requiring "either (1) likelihood of success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the party requesting the preliminary relief." *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979).[11]

d. Congress has recognized the importance of risk analysis in injunctive settings when it codified public nuisance principles in various environmental laws. Courts have done the same in applying those provisions.

In the environmental realm, risk assessment principles manifest themselves in various ways.[12] The

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[11] Black's Law Dictionary has gone even further in relaxing the likelihood standard, defining the likelihood-of-success-on-the-merits test as requiring only "a reasonable probability of success in the litigation or appeal." Black's Law Dictionary 947 (8th ed 2004); *see also AlliedSignal, Inc v. B.F. Goodrich Co.*, 183 F.3d 568, 576 (7th Cir. 1999) (applying an unquantified "substantial likelihood of irreparable harm" test in an antitrust case).

[12] Under some environmental statutes, certain harms are seen as being so serious that our laws speak in absolute terms. The most famous example of this is the Endangered Species Act, under which, as this Court has recognized, in barring harm to endangered species or their critical habitat, "Congress has

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place where Congress has made most apparent its embrace of risk assessment principles specifically in the injunctive relief context is in the so-called "imminent hazard" provisions in several pollution control statutes. *See, e.g.*, 42 U.S.C. §§ 6973, 9606. Congress expressly patterned these provisions on public

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spoken in the plainest of terms, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978) (applying 16 U.S.C. § 1536(a)). In other contexts, Congress and/or the agencies that implement the relevant statutes have set substantive standards according to what they deem to be acceptable risk ranges given the perceived severity of the potential adverse effects. Under the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601, *et seq.*, for example, the Environmental Protection Agency must clean up sites to a degree that reduces the cancer threat to those living nearby to a risk range of between one-in-ten-thousand ($1x10^{-4}$) and one-in-a-million ($1x10^{-6}$), with the latter standard serving as the "point of departure." 40 C.F.R. § 300.430(e)(2)(i)(A)(2); *see also* 42 U.S.C. § 9621(b)(1). In the nuclear context, the Nuclear Regulatory Commission's design requirements for nuclear power plants contemplate that siting decisions control for "design basis events." These requirements generally ensure that these facilities will not release significant radiation levels during events (such as aircraft accidents) that are found to have more than a one-in-ten-million chance of occurring. *See, e.g.*, 10 C.F.R. §§ 52.17, 52.79, 100.10, 100.20, 100.21; NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (SRP), Section 3.5.1.6, "Aircraft Hazards" (Rev. 4, Mar. 2010) (ML070510639), at 3.5.1.6-4 (providing that Part 52 and Part 100 regulations are satisfied "if the probability of aircraft accidents resulting in radiological consequences greater than the 10 [C.F.R.] Part 100 exposure guidelines is less than order of magnitude of 10^{-7} [one in ten million] per year").

nuisance principles. *See, e.g.*, S. Rep. No. 96-172., 1st Sess., at 5, *as reprinted in* (1980) U.S.C.C.A.N. 5019, 5023; *see also United States v. Waste Indus., Inc.*, 734 F.2d 159 (4th Cir. 1984).

Sections 7002(a)(1)(B) and 7003 of the Resource Conservation and Recovery Act, 42 U.S.C. § 6972(a)(1)(B) and 6973, are typical of these provisions. Under these provisions, Congress empowered the courts to issue injunctions, at either citizens' or the Government's behest (respectively), whenever the handling or disposal of any solid or hazardous waste "may present an imminent and substantial endangerment to health or the environment." In keeping with this language, courts have found that Congress authorized relief whenever there is a "reasonable cause for concern that someone or something may be exposed to a risk of harm by a release or a threatened release of a hazardous substance if remedial action is not taken." *Interfaith Comty. Org. v. Honeywell Int'l., Inc.*, 399 F.3d 248, 259 (3d Cir. 2005) (upholding injunction in a citizen suit).[13] In *Reserve Mining Co. v. Environmental Protection Agency*, 514 F.2d 492 (8th Cir. 1975), the Eighth Circuit elaborated on this idea in a case involving a predecessor to the Clean Water Act's current "imminent hazard" provision:

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[13] *See also United States v. Conservation Chem. Co.*, 619 F. Supp. 162, 194 (W.D. Mo. 1985) (applying the same standard under § 106 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9606).

> These concepts of potential harm, whether they be assessed as "probabilities and consequences" or "risk and harm," necessarily must apply in a determination of whether any relief should be given in cases of this kind in which proof with certainty is impossible. The district court, although not following a precise probabilities-consequences analysis, did consider the medical and scientific evidence bearing on both the probability of harm and the consequences should the hypothesis advanced by the plaintiffs prove to be valid.
>
> In assessing probabilities in this case, it cannot be said that the probability of harm is more likely than not. Moreover, the level of probability does not readily convert into a prediction of consequences. On this record it cannot be forecast that the rates of cancer will increase from drinking Lake Superior water or breathing Silver Bay air. The best that can be said is that the existence of this asbestos contaminant in air and water gives rise to a reasonable medical concern for the public health. The public's exposure to asbestos fibers in air and water creates some health risk. Such a contaminant should be removed.

Id. at 520.

II. *WINTER* DID NOT ALTER THE TRADITIONAL EQUITABLE REQUIREMENTS FOR AN INJUNCTION.

In *Winter*, this Court indicated that the Ninth Circuit had erred in determining that any "possibility" of irreparable injury was sufficient to satisfy the irreparable injury threshold in NEPA cases. 129 S. Ct. at 375 (citing, *inter alia*, *Faith Center Church Evangelistic Ministries v. Glover*, 480 F.3d 891, 906 (9th Cir. 2007)). Significantly, however, the Court did not articulate the circumstances in which an actual threat of significant harm can constitute a sufficient likelihood of irreparable injury. Nor did it indicate that it was altering the traditional principles of equitable relief in any way; to the contrary, the Court's entire discussion is framed as an application of those basic principles. *Id.* at 374-82.

Moreover, specifically with regard to the "likelihood of irreparable injury" standard, the *Winter* Court declined to make any finding regarding whether the plaintiff had met the equitable test. Instead, despite the Navy's contention that there had been no documented harm to marine mammals during 40 years of similar training in the relevant area, the Court specifically rested its holding on other grounds, concluding that "even if plaintiffs have shown irreparable injury from the Navy's training exercises, any such injury is outweighed by the public interest and the Navy's interest in effective, realistic training of its sailors." *Id.* at 376.

Monsanto's argument in this case is wholly premised on the idea that *Winter* altered the traditional equitable test regarding the likelihood of irreparable injury. *See* Petr.'s Br. 41-47. *Winter*, however, did no such thing. The Court's "irreparable injury" discussion in *Winter* simply cannot bear the weight Monsanto puts on it.

III. THAT NEPA IMPOSES ONLY PROCEDURAL MANDATES SHOULD NOT UNDERMINE THE ABILITY OF THE COURTS TO ENJOIN ACTIONS THAT WILL LIKELY LEAD TO IRREPARABLE INJURY.

Most environmental statutes contain enforceable substantive mandates. *See, e.g.*, 33 U.S.C. § 1311(b) (Clean Water Act). In that context, it may be that violations of those standards should constitute irreparable harm as a matter of law. This conclusion would seem consistent with *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) ("*Oakland Cannabis*"). In that case, this Court held that:

> . . . [A] court sitting in equity cannot ignore the judgment of Congress, deliberately expressed in legislation. A district court cannot, for example, override Congress' policy choice, articulated in a statute, as to what behavior should be prohibited. Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is . . . for the courts to enforce them

> when enforcement is sought. Courts of equity cannot, in their discretion, reject the balance that Congress has struck in a statute. Their choice (unless there is statutory language to the contrary) is simply whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all. Consequently, when a court of equity exercises its discretion, it may not consider the advantages and disadvantages of nonenforcement of the statute, but only the advantages and disadvantages of employing the extraordinary remedy of injunction over other available methods of enforcement. To the extent the district court considers the public interest and the conveniences of the parties, the court is limited to evaluating how such interest and conveniences are affected by the selection of an injunction over other enforcement mechanisms.

Oakland Cannabis, 532 U.S. at 497-498 (internal quotations and footnotes omitted).[14]

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[14] *See also Tenn. Valley Auth. v. Hill*, 437 U.S. 153 (1978), and *United States v. Mass. Water Res. Auth* , 256 F.3d 36, 51 n.15 (1st Cir. 2001) *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982), is not to the contrary. Indeed, a careful reading of it supports this position. In *Romero-Barcelo*, this Court upheld the district court's decision not to enjoin the relevant discharges under § 309(b) of the Clean Water Act, 33 U.S.C. § 1319(b). It did so under the equitable-balancing prong of the injunctive-relief calculus, and in a context in which the relevant violation was

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While this Court has determined that NEPA "imposes on agencies duties that are essentially procedural," *Strycker's Bay Neighborhood Council, Inc. v. Karlen*, 444 U.S. 223, 227 (1980), it also has recognized that the statute has broad substantive goals. *Id.; see also Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350-51 (1989). Among its other objectives, Congress sought through NEPA to "assure for all Americans safe, healthful, productive, and esthetically pleasing surroundings." 42 U.S.C. § 4331(b)(2). That Congress sought to achieve these goals through procedural means does not undermine the seriousness of the goals themselves. As this Court noted:

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procedural – the failure to obtain a permit – not substantive. *Id.* at 312-19. The Court concluded that "the integrity of the Nation's waters, . . . not the permit process, is the purpose of the [Clean Water Act]." *Id* at 314 The Court did not, however, find an absence of irreparable harm, even though it emphasized the lower court's finding that that the relevant discharges were not causing any measureable harm to the waters. *Id.* at 310. The Court underscored the limited nature of its pronouncement in its penultimate paragraph:

> . . . The District Court did not face a situation in which a permit would very likely not issue, and the requirements and objective of the statute could therefore not be vindicated if discharges were permitted to continue. *Should it become clear that no permit will be issued and that compliance with [the Act] will not be forthcoming, the statutory scheme and purpose would require the court to reconsider the balance it has struck.*

Id at 320 (emphasis added).

> The sweeping policy goals announced in § 101 of NEPA are [to be] realized through a set of action-forcing procedures that require that agencies take a hard look at environmental consequences, and that provide for broad dissemination of relevant environmental information. . . .

Methow Valley, 490 U.S. at 350 (internal quotations omitted). The *Methow Valley* Court also noted that "these procedures are almost certain to affect the agency's substantive decision." *Id.*

The plaintiffs in this case have a legal injury and cannot be adequately compensated by monetary damages.[15] Additionally, the real-world threats here at issue are serious and have not been adequately studied, as required by Congress. In situations where, as here, there is a reasonable prospect of significant harm, lower courts should have the discretion to determine whether an agency's failure to comply with the law entails a sufficient likelihood of irreparable injury to support equitable relief. This is particularly true in the context of a statute such as NEPA, where Congress has expressly recognized "the critical importance of . . . maintaining environmental quality," 42 U.S.C. § 4331(a), and "direct[ed] that, to the fullest extent possible: (1) the policies, regulations, and

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[15] *See Amoco Production Co. v. Village of Gambell*, 480 U.S. 531, 545 (1987) ("[e]nvironmental injury, by its nature, can seldom be adequately remedied by money damages and is often permanent or at least of long duration, *i.e.*, irreparable").

public laws of the United States shall be interpreted and administered in accordance with [NEPA's] policies. . . . " 42 U.S.C. § 4332.

In other contexts this Court has not hesitated to invoke its equitable powers to address procedural violations in the absence of any affirmative demonstration of a preponderant likelihood of substantive irreparable harm. In *Clark v. Roemer*, 500 U.S. 646 (1991), for example, the Court dealt with a violation of the "preclearance" provisions in § 5 of the Voting Rights Act of 1965, 42 U.S.C. § 1973c. In that case, the district court had allowed both an election to go forward and the winners to assume their offices (at least provisionally), despite violations of § 5. A unanimous Court reversed, holding that the district court was required to enjoin the illegal election. *Id.* at 654. The Court did this without any inquiry into whether the plaintiffs had shown that the procedural violation – the State's failure to obtain preclearance – had led or was likely to lead to any irreparable harm.[16]

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[16] In a later case, the Court made clear that the presence or absence of harm is not an issue in preclearance cases:

> Nor does it matter for the preclearance requirement whether the change works in favor of, works against, or is neutral in its impact upon the ability of minorities to vote. . . . [P]reclearance is a process aimed at preserving the status quo until the Attorney General or the courts have an opportunity to evaluate a proposed change.

Young v. Fordice, 520 U.S. 273, 285 (1993) (internal citations omitted).

Instead, the Court announced a nearly automatic rule that injunctions should issue in these contexts:

> We need not decide today whether there are cases in which a district court may deny a § 5 plaintiff's motion for injunction and allow an election for an unprecleared seat to go forward. An extreme circumstance might be present if a seat's unprecleared status is not drawn to the attention of the State until the eve of the election and there are equitable principles that justify allowing the election to proceed. No such exigency exists here.

Id. at 654-655; *see also Branch v. Smith*, 538 U.S. 254 (2003).

Of course, NEPA is not the Voting Rights Act. However, NEPA plaintiffs such as Geertson Seed Farms stand to suffer substantive and legally cognizable injuries, which may be avoided if the required procedures are followed. And, as in this case, the real world harms at stake in NEPA cases can be quite significant.[17] Moreover, the NEPA process can and

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[17] *See also Sierra Club v. U.S. Army Corps of Eng'rs.*, 701 F.2d 1011 (2d Cir. 1983) (Corps was poised to fill in a "highly significant and productive habitat" for striped bass in the Hudson River, which was the second most important contributor of those fish in the Atlantic Coast fishery), *Found. on Econ. Trends v. Weinberger*, 610 F Supp. 829 (D.D.C. 1985) (finding that the Army had failed to consider "serious and farreaching" risks relating to the use of pathogenic agents and toxins at a test laboratory), and *Sierra Club v. Coleman*, 405 F. Supp. 53, 55 (D.D.C. 1975) (finding that the Federal Highway Administration failed to adequately address the risks of aftosa, which the record

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often does make a substantive difference. Again, in *Methow Valley* this Court deemed that prospect "almost certain." 490 U.S. at 350. Indeed, as this Court noted in *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n.7 (1992), it is that very possibility that gives those who live near proposed federal projects redressability for Article III purposes.

Courts have always construed the elements required for equitable relief in a flexible fashion, with due deference to trial court judges. As seen above, the "likelihood of irreparable injury" standard is perfectly well suited to averting substantial risks of significant harm, even absent a preponderant likelihood that the harm will come to pass. In the NEPA context, there may certainly be some cases where the threat of significant harm is so minor that the legal injury any potential plaintiffs could suffer should not, by itself, be deemed to meet the irreparable injury requirement. This case, however, is not one of them.

Respectfully submitted,

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revealed could have resulted in the destruction of 25% of North American livestock if not adequately contained)

APPENDIX

Description of *Amici Curiae*

The Natural Resources Defense Council is one of the nation's leading environmental organizations, with 1.2 million members and supporters. Its mission is to safeguard the Earth: its people, its plants and animals and the natural systems on which all life depends.

Craig N. Johnston is a professor of law at Lewis & Clark Law School, where he teaches courses in environmental law and environmental enforcement, among other courses. Prof. Johnston also has co-authored casebooks in both environmental law and hazardous waste law.

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AMICUS CURIAE BRIEF

No. 09-475

In the

Supreme Court of the United States

MONSANTO CO., et al.,

Petitioners,

v.

GEERTSON SEED FARMS, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

In this case, after finding a violation of the National Environmental Policy Act ("NEPA"), the district court imposed, and the Ninth Circuit affirmed, a permanent nationwide injunction against any further planting of a valuable genetically-engineered crop, despite overwhelming evidence that less restrictive measures proposed by an expert federal agency would eliminate any non-trivial risk of harm. The questions presented are:

1. Whether the Ninth Circuit erred in holding that NEPA plaintiffs are specially exempt from the requirement of showing a likelihood of irreparable harm to obtain an injunction.

2. Whether the Ninth Circuit erred in holding that a district court may enter an injunction sought to remedy a NEPA violation without conducting an evidentiary hearing sought by a party to resolve genuinely disputed facts directly relevant to the appropriate scope of the requested injunction.

3. Whether the Ninth Circuit erred when it affirmed a nationwide injunction entered prior to this Court's decision in *Winter v. NRDC*, 129 S. Ct. 365 (2008), which sought to remedy a NEPA violation based on only a remote possibility of reparable harm.

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IDENTITY AND INTEREST OF AMICUS CURIAE[1]

Under Supreme Court Rule 37, Pacific Legal Foundation (PLF) respectfully submits this brief amicus curiae in support of Petitioner Monsanto Co.

PLF was founded over 35 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. PLF advocates for limited government, individual rights, free enterprise, and a balanced approach to environmental regulation. PLF has participated in a number of this Court's cases dealing with the availability of injunctive relief for violations of federal environmental laws. *See, e.g., Winter v. Natural Res. Def. Council*, 129 S. Ct. 365 (2008); *Amoco Prod. Co. v. Village of Gambell, Alaska*, 480 U.S. 531 (1987).

PLF's analysis of the law of injunctions and their availability will provide a valuable, additional viewpoint to assist the Court in resolving the case.

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[1] Pursuant to this Court's Rule 37.3(a), all parties have consented to the filing of this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

INTRODUCTION AND SUMMARY OF ARGUMENT

As tribunals of limited jurisdiction, federal courts are restricted not just in the types of actions that they may hear, but also in the remedies they may afford. Federal courts' power to issue injunctions is a function of their equity jurisdiction, *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982), which derives ultimately from Article III of the United States Constitution, and mediately from Section 11 of the Judiciary Act of 1789, 1 Stat. 73, 78 (Sept. 24, 1789). *See Grupo Mexicano de Desarrollo, S.A. v. Alliance Bond Fund, Inc.*, 527 U.S. 308, 318 (1999). The traditional requirements for entitlement to permanent injunctive relief—likelihood of irreparable harm, favorable balance of equities, and consideration of the public interest, *see Romero-Barcelo*, 456 U.S. at 312-13—generally circumscribe federal courts' power to issue an injunction in all types of cases, including those arising, as here, under the National Environmental Policy Act (NEPA), 42 U.S.C. § 4321, *et seq.* *See Winter*, 129 S. Ct. at 376-78.

The Ninth Circuit Court of Appeals' affirmance of a district court's nationwide injunction preventing the use of Roundup Ready Alfalfa, based on a NEPA violation, conflicts in two important respects with these basic limitations on federal courts' ability to issue injunctive relief. First, the nationwide injunction was issued on the grounds of the possibility of irreparable harm occurring if the relief were not ordered, rather than under the traditional, and more stringent, standard of likelihood of irreparable injury. Second, the injunction was issued without the district court having conducted an evidentiary hearing, even

though facts essential to the propriety of the injunction—including whether irreparable harm would result without an injunction—were vigorously disputed by the parties. And contrary to the Ninth Circuit's conclusion, none of these departures from the traditional standards for granting equitable relief can be excused because the injunction arises from a NEPA claim.

ARGUMENT

I

A PARTY SEEKING AN INJUNCTION MUST ESTABLISH THAT, ABSENT THE INJUNCTION, IT IS LIKELY THAT THE PARTY WILL SUFFER IRREPARABLE HARM

One of the traditional elements of injunctive relief is establishing a likelihood of irreparable harm. *E.g.*, *Winter*, 129 S. Ct. at 375. The Ninth Circuit below held that the district court had correctly found that, absent an injunction barring use of modified alfalfa, irreparable harm through genetic contamination was "sufficiently likely to occur so as to warrant broad injunctive relief." Petitioner's Appendix (Pet. App.) at 13a (*Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1137 (9th Cir. 2009)). But the district court issued its injunction in May, 2007, *see* Pet. App. at 79a, before *Winter* was decided, and thus necessarily applied the Ninth Circuit's then-regnant "possibility of irreparable harm" standard. *Cf. Earth Island Inst. v. U.S. Forest Serv.*, 442 F.3d 1147, 1177 (9th Cir. 2006) ("Because Earth Island has shown 'a strong likelihood of success on the merits,' it need only show 'the possibility of irreparable injury' if preliminary relief is not

granted . . . ."). That relaxed standard is flatly inconsistent with the traditional standard for injunctive relief, and cannot be reconciled with federal courts' equity jurisdiction under the 1789 Judiciary Act and Article III.

The injunctive power of federal courts is coextensive with that enjoyed by the English High Court of Chancery at the time of separation between Great Britain and this country. *See Grupo Mexicano*, 527 U.S. at 318. Absent authorization from Congress, the federal judiciary may not provide an equitable remedy that, in 1789, would have been unknown to the English Chancery. *See id.* at 327, 332-33. *See also Baker v. Biddle*, 2 F. Cas. 439, 447-48, No. 764 (C.C.E.D. Pa. 1831) (Baldwin, C.J.) ("It follows that new rules subversive of established principles and practice [of equity] are excluded.").

Chancery was considered to have two bases of jurisdiction, one ordinary and one extraordinary. 4 Lord Edward Coke, *Institutes of the Laws of England* 79 (1986 reprint) (1797 ed. London); *see also* 3 William Blackstone, Commentaries *47. The latter, from which arises the injunctive power, was firmly established long before the Revolution of 1689. *See* 1 Joseph Story, *Commentaries on Equity Jurisprudence as Administered in England and America* 37-39 (13th ed. 1886) (1835). The purpose of the equity power, as traditionally understood, was to make right and just (*ex aequo et bono*) those instances where the general

law was lacking. *Id.* at 3-4[2]; *see also* 1 Story, *supra*, at 4 n.2 ("'Properly and particularly, however, equity is the power of will, its corrector, by which the law on account of its universality is lacking.'") (quoting Grotius, De Aequitate, Ch. 1, § 2). As a technical matter, of course, equitable remedies followed upon legal remedies, and the Chancellor was as bound by rules as the courts of law. *See* 1 Story, *supra*, at 17-19. *Cf.* 4 Blackstone, Commentaries *50 ("In these early times the chief judicial employment of the chancellor must have been in devising new writs, directed to the courts of common law, to give remedy in cases where none was before administered."). But the undeniably expansive power of equity brought with it a responsibility to exercise discretion as well as a freedom to craft a well-tailored remedy. *See* 1 Story, *supra*, at 21 ("[O]ne of the most striking and distinctive features of Courts of Equity is that they can adapt their decrees to all the varieties of circumstances which may arise, and adjust them to all the peculiar rights of all the parties in interest . . . ."); 2 Story, *supra*, at 183, 262. It is no surprise that the Chancellor's discretion came to be carefully circumscribed by rules limiting the availability of injunctive relief.[3]

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[2] Citing, *inter alia*, Nicomachean Ethics Bk. 5, ch. 10, ll. 27-28 (W.D. Ross trans., 1941) ("And this is the nature of the equitable, a correction of law where it is defective owing to its universality.").

[3] In fact, Mr. Justice Story strongly cautioned against the abuse of the equity power.

> The jurisdiction of these courts thus operating by way of special injunction is manifestly indispensable for the purposes of social justice in a great variety of cases, and therefore should be fostered and upheld by a steady

(continued...)

Among these rules were the requirements for entitlement to injunctive relief, whether preliminary or permanent.[4] From equity's earliest days, likelihood of irreparable harm had to be shown before any type of injunction would issue. *See* John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 527, 531 (1978). Traditionally, injunctive relief was available from the equity courts to, among other things, protect rights at law. *Id.* at 528-29. In such cases, litigants would seek recourse in equity because the available legal remedies were inadequate; without equity's intervention the litigants would be irreparably harmed. *Id.* at 529. *Cf.* 4 Co. Inst. 84 ("Never recourse to extraordinary [jurisdiction] except where ordinary [jurisdiction] is deficient."); 1 Story, *supra*, at 40; 2 Story, *supra*, at 184.

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[5] (...continued)

> confidence. At the same time it must be admitted that the exercise of it is attended with no small danger both from its summary nature and its liability to abuse. It ought therefore to be guarded with extreme caution and applied only in very clear cases; otherwise instead of becoming an instrument to promote the public as well as private welfare, it may become a means of extensive and perhaps of irreparable injustice.

See 2 Story, *supra*, at 264.

[6] As this Court has noted, the standard for preliminary injunction, with respect to the necessity of irreparable harm, is identical to that for permanent injunction. *Winter*, 129 S. Ct. at 381; *Amoco*, 480 U.S. at 546 n.12.

"Irreparable injury thus became a source of equity jurisdiction in preliminary as well as final adjudications."[5] Several leading early equity cases confirm that observation. *See, e.g.*, *Mogg v. Mogg*, 21 Eng. Rep. 432, 433 (Ch. 1786) (noting that, "until such [disputed] right [at law] was determined, it was very proper to stay [the defendants] from doing an act, which if it turned out they had no right to do, would be irreparable"); *Ryder v. Bentham*, 27 Eng. Rep. 1194, 1194-95 (Ch. 1750) (granting an injunction to remove light-blocking scaffolding because equity would not order the removal of a building, and because, if the defendant continued to construct during the pendency of the action but the plaintiff should prove successful in the action, the latter's lights would be permanently blocked and he would be irreparably harmed); *Johnson v. Goldswaine*, 145 Eng. Rep. 1027, 1028 (Ex. 1796)[6] (denying injunction on the grounds that "this was not a case of irreparable injury, which is the only ground of this summary interposition of Courts of Equity"). *See also* 2 Story, *supra*, at 229 (discussing availability

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[5] Leubsdorf, *supra*, at 530. By the eighteenth century, Chancery was authorized to grant provisional relief either through a "common order," used (among other reasons) to constrain actions in the law courts, or through a "special order," used to protect rights at law during the pendency of a suit in equity. Note, *Probability of Ultimate Success Held Unnecessary for Grant of Interlocutory Injunction*, 71 Colum. L. Rev. 165, 166 (1971); *see* 2 Story, *supra*, at 201. These special orders, which are the closest analogue to the injunction at issue here, were issued only after the movant had "demonstrate[d] a strong probability of immediate irreparable damage to his property." 71 Colum L. Rev. at 166. *See* 2 Story, *supra*, at 229, 234.

[6] The Court of Exchequer developed prior to the eighteenth century an equity jurisdiction similar to that of Chancery in which proceedings were begun by "English Bill."

of the writ of injunction for private nuisances) ("So a mere diminution in the value of property by the nuisance without irreparable mischief will not furnish any foundation for equitable relief."). *Cf id.* at 234 ("For if the trespass be fugitive and temporary, and adequate compensation can be obtained in an action at law, there is no ground to justify the interposition of Courts of Equity.").[7]

The foregoing underscores that an essential element to entitlement to injunctive relief is the establishment of irreparable harm in the absence of such relief. The power of a federal court is no more, no less, than that of the Chancellor at Westminister at the time of separation. *See Grupo Mexicano*, 527 U.S. at 318. A review of the authorities nearest in time to that crucial point makes plain that the pre-*Winter* standard used by the Ninth Circuit to uphold a permanent injunction barring use of Roundup Ready Alfalfa is irreconcilable with those authorities. This Court should affirm its prior holdings, and the centuries-old common law tradition, and confirm that a NEPA injunction cannot issue without adequate and competent proof of likelihood of irreparable harm.

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[7] *Accord* John Adams, Jr., *The Doctrine of Equity* 185-86 (1850).

II

DISPUTED ISSUES OF FACT MATERIAL TO THE ELEMENTS OF INJUNCTIVE RELIEF MUST BE RESOLVED THROUGH AN EVIDENTIARY HEARING

A centerpiece of Anglo-American common law procedural protections is the right to the resolution of essential factual issues by a trier of fact following adversarial presentation of evidence, including live testimony. *United States v. Microsoft*, 253 F.3d 34, 101 (D.C. Cir. 2001) (en banc) ("It is a cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings."). *See Sims v. Greene*, 161 F.2d 87, 88 (3d Cir. 1947) (disputed issues of fact pertinent to a preliminary injunction "must be resolved by oral testimony," otherwise the trial court "will be left in the position of preferring one piece of paper to another"). *See also SEC v. Frank*, 388 F.2d 486, 491 (2d Cir. 1968) (Friendly, J.) ("[W]here everything turns on what happened and that is in sharp dispute[,] . . . the inappropriateness of proceeding on affidavits attains its maximum . . . ."). *Cf. Southern Ry. Co. v. Commonwealth of Virginia ex rel. Shirley*, 290 U.S. 190, 195, 199 (1933) (statute giving administrative officer "power to make final determination in respect of facts . . . without notice, without hearing, without evidence" held violative of due process); *Ohio Bell Tel. Co. v. Pub. Utils. Comm'n of Ohio*, 301 U.S. 292, 304-05 (1937) (noting that "the 'inexorable safeguard' of a fair and open hearing . . . is one of 'the rudiments of fair play'" for which "[t]here can be no compromise on the footing of convenience or expediency, or because of a

natural desire to be rid of harassing delay, when that minimal requirement has been neglected or ignored" (citations omitted)).

This ancient common law tradition, maintained through the Court's precedents, is also consistent with the Federal Rules of Civil Procedure, which require that preliminary injunctions be preceded by a hearing, Fed. R. Civ. P. 65(a)(2), (b)(3), and mandate that every injunction be accompanied by findings, *see id.* 52(a)(1)-(2). *See also Fengler v. Numismatic Americana, Inc.*, 832 F.2d 745, 747 (2d Cir. 1987) ("On a motion for preliminary injunction, 'where essential facts are in dispute, there must be a hearing . . . and appropriate findings of fact must be made.") (quoting *Visual Sciences, Inc. v. Integrated Commc'ns, Inc.*, 660 F.2d 56, 58 (2d Cir. 1981)); 11A Fed. Prac. & Proc. Civ. § 2949 (2d ed. 1995) ("When the outcome of a Rule 65(a) application depends on resolving a factual conflict by assessing the credibility of opposing witnesses, it seems desirable to require that the determination be made on the basis of their demeanor during direct and cross-examination, rather than on the respective plausibility of their affidavits."). *Cf. Morgan v. United States*, 304 U.S. 1, 20 (1938) ("The requirements of fairness are not exhausted in the taking or consideration of evidence, but extend to the concluding parts of the procedure as well as to the beginning and intermediate steps."); *Carter v. Kubler*, 320 U.S. 243, 247 (1943) (holding that "a full and fair hearing" includes the right "to examine, explain or rebut" all evidence).

These ancient, hoary precepts of the common law and due process forbid an injunction to issue without those persons enjoined having been given an

opportunity to examine their opponents in open court and to question them on the evidence supposedly supporting the injunction. The injunction approved by the Ninth Circuit below is inconsistent with these protections. The Court should therefore affirm these common law protections by overturning the injunction.

III

THE TRADITIONAL REQUIREMENTS FOR INJUNCTIVE RELIEF CANNOT BE RELAXED MERELY BECAUSE THE UNDERLYING LEGAL CLAIM ARISES UNDER THE NATIONAL ENVIRONMENTAL POLICY ACT

This Court has frequently observed that the traditional requirements for injunctive relief presumptively apply to all types of cases, *see Amoco*, 480 U.S. at 542; *Romero-Barcelo*, 456 U.S. at 313, including NEPA cases, *see Winter*, 129 S. Ct. at 376-78. The Ninth Circuit approved the district court's dramatic departure from the traditional elements of entitlement to injunctive relief, on the grounds that NEPA injunctions are different in kind and quality from other types of injunctions, a difference that purportedly authorizes a relaxation of these traditional requirements. *See* Pet. App. at 18a-19a (*Geertson Seed Farms*, 570 F.3d at 1139-40). This Court should therefore affirm its precedents to state, once again, that NEPA does not authorize a relaxation of the traditional elements of injunctive relief, for the following reasons.

First, that NEPA injunctions are limited in time and expire once the agency has completed the necessary environmental impact analysis justifies nothing. Permanent injunctions are frequently not *sine fine*, instead ending once the complained of injury has been remedied or the underlying case otherwise becomes moot.[8] *See, e.g.*, *Sweeton v. Brown*, 27 F.3d 1162, 1166 (6th Cir. 1994) (en banc) ("Ongoing injunctions should be dissolved when they no longer meet the requirements of equity."); *Western Union Tel. Co. v. Intn'l Bhd. of Elec. Workers, Local No. 134*, 133 F.2d 955, 957 (7th Cir. 1943) ("[An injunction] is executory and continuing as to the purpose or object to be acquired, and operates until vacated, modified, or dissolved . . . ."). Moreover, that NEPA injunctions may be shorter in duration than other injunctions was no obstacle to this Court ruling in *Winter* that the traditional elements of entitlement to injunctive relief must be proved up as much in the NEPA context as in others. *Cf. Winter*, 129 S. Ct. at 375-78.

Second, it is irrelevant that the environmental impact analysis that the agency would conduct on remand may parallel the analysis that the district court would conduct in an evidentiary hearing to determine irreparable harm. As Judge Smith noted in dissent below, "the district court did not need to

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[8] *Cf.* Fed. R. Civ. P. 60(b)(5) (authorizing relief from final order or decree if it "has been satisfied, released or discharged . . . or applying it prospectively is no longer equitable"); *Agostini v. Felton*, 521 U.S. 203, 215 (1997) ("A court errs when it refuses to modify an injunction or consent decree in light of . . . changes" "in factual conditions or in law."); *Poor v. Carleton*, 19 F. Cas. 1013, 1014, No. 11,272 (C.C. Mass. 1837) (Story, J.) (common injunction [as opposed to special injunction] should be dissolved once defendant has made appearance by way of answer).

resolve the very disputes over the risk of environmental harm" because the court "only needed to decide, listening and observing the witnesses, what it would do in the mean time." Pet. App. at 24a (*Geertson Seed Co.*, 570 F.3d at 1143 (Smith, J., dissenting)). In other words, an evidentiary hearing would only require the district court to determine whether irreparable harm would be likely to befall the plaintiffs pending preparation of an environmental impact statement; the court would not need to determine whether or to what extent the proposed project would produce significant effects on some aspect of the human environment. And as this Court observed in *Winter*, the district courts retain jurisdiction to craft NEPA remedies, "including declaratory relief or an injunction tailored to the preparation of an [environmental impact statement]." *Winter*, 129 S. Ct. at 381.

Hence, by overturning the injunction, this Court can confirm NEPA does not allow for a weakening of the standard requirements for entitlement to injunctive relief.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be reversed.

DATED: March, 2010.

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AMICUS CURIAE BRIEF

No. 09-475

In The Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF AMICI CURIAE PEOPLE OF THE STATE OF CALIFORNIA *EX REL.* EDMUND G. BROWN JR., ATTORNEY GENERAL; COMMONWEALTH OF MASSACHUSETTS, MARTHA COAKLEY, ATTORNEY GENERAL; STATE OF OREGON, JOHN R. KROGER, ATTORNEY GENERAL IN SUPPORT OF RESPONDENTS

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Amici respectfully submit this brief pursuant to Rule 37.4 of the Rules of the United States Supreme Court, in support of respondents Geertson Seed Farms, *et al.*

INTEREST OF THE AMICI CURIAE

States have an obvious interest in the federal government's compliance with laws that Congress enacted to protect the environment. One of the most important of those laws is the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-4347, "our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a) (2009). It requires federal agencies to take a hard look at the potential environmental consequences of their proposed actions, and to inform the public about those consequences, *before* the agencies proceed. 42 U.S.C. § 4332. When a federal agency fails to do so, as here, it affects the States' interests in protecting their natural resources and their citizens' rights to be informed about the environmental impacts of federal actions.

Although this case concerns the federal deregulation of genetically modified seed, the issues raised extend beyond the specific facts of this case. They involve the proper scope of an injunction and the nature of irreparable harm when a federal agency proposes to take actions before it has complied with NEPA. The case also raises the question of whether the district

court must hold trial-type evidentiary hearings to resolve factual disputes about the environmental impacts of proposed actions, when the federal agency is required to evaluate and determine those very same impacts through the NEPA review process. These issues arise during the remedy phase of nearly all cases in which the federal government violates NEPA, and are of vital concern to the States.

Over one hundred years ago, this Court recognized that a State has significant interests "independent of and behind the titles of its citizens, in all the earth and air within its domain." *State of Georgia* v. *Tennessee Copper Co.*, 206 U.S. 230, 237 (1907). Those same interests were recognized more recently by this Court in *Massachusetts* v. *Environmental Protection Agency,* 549 U.S. 497, 518-21 (2007).

The potential for federal actions to affect these state interests is immense. Proposed federal actions raise environmental concerns of many types, including protection of wilderness, habitat preservation for endangered species, watershed protection, air quality, off-shore drilling in coastal areas, development and movement of petroleum and natural gas, movement and storage of nuclear waste, building of power plants in the desert and transmission lines across public lands, and many more.

Consistent with their duty to protect their resources, the States of California and Oregon,

and the Commonwealth of Massachusetts have, on numerous occasions, filed suit to challenge federal actions that failed to comply with NEPA, and have successfully obtained injunctions that prevent federal agencies from acting until they have completed the required environmental review. Injunctions requiring the agency to cease the proposed activity pending compliance with NEPA often profoundly affect the project or the proposed action. In some cases, after the required environmental review occurs, the project is changed to avoid environmental impacts; in others, additional mitigation is required; and in still others, the project is shelved in light of its true costs and risks.

The environmental harm that will occur directly from a proposed federal action is often apparent and undisputed—acres of trees will be cut, or a river will be dammed—making the plaintiff's showing of likely irreparable harm a straightforward exercise. There are, however, occasions when the harm is a matter of significant dispute. The proposed action may involve unprecedented risks, new technology, or may operate in an area where the science is as yet undeveloped or uncertain. In those situations, it may be impossible for the States, the public at large, and the courts to ascertain with certainty the full extent of the harm that is likely to result from the proposed action. Indeed, it would be surprising if they could, because the agency's violation leaves them without a full and

objective analysis of all of the potential environmental consequences and reasonable alternatives that must be considered.

When an inadequate environmental review impairs the ability of a challenger to establish with certainty the harm that is likely to occur from a proposed action, permitting a federal agency to proceed without the review required by NEPA heightens the risks to the environment and effectively rewards the federal agency for its failure to study the impacts of its actions. Thus, this Court's formulation of irreparable harm under NEPA and the discretion of the district courts in shaping injunctive relief will directly affect the ability of the States and their citizens to participate fully in the NEPA review process, to ensure the integrity of that process, and to protect their natural resources.

SUMMARY OF ARGUMENT

It is settled that a plaintiff seeking a permanent injunction must meet the traditional four-part test for injunctive relief. To do so, the plaintiff must demonstrate that irreparable harm is likely, the remedies available at law are inadequate, the balance of hardships warrants injunctive relief, and the public interest would not be disserved by a permanent injunction. *eBay* v. *MercExchange, LLC*, 547 U.S. 388, 391 (2006).

In fashioning injunctive relief and determining what constitutes irreparable harm, courts must consider the purpose and language of the statute at issue, not merely the fact of a statutory violation. NEPA is a procedural statute that requires federal agencies to evaluate and consider environmental consequences and values before they make a decision or take an action that may have a significant impact on the environment. 42 U.S.C. § 4332(C). In *Winter* v. *Natural Resources Defense Council*, this Court recognized that part of the particular harm that NEPA seeks to prevent is the harm that arises when an agency acts with little information about potential environmental harms and mitigation measures. __ U.S. __, 129 S. Ct. 365, 376 (2008).

Thus while there are situations in which actions should be permitted to proceed pending completion of the environmental review, a district court has discretion to enjoin actions when the lack of information poses too great a risk of the harms against which NEPA is intended to protect. An injunction therefore may be warranted where (1) there is a substantial dispute or insufficient information about the potentially serious and irreparable environmental effects of an action, such that the NEPA review process would provide the information necessary to evaluate those risks before proceeding; or (2) implementation of the action may foreclose consideration of other, potentially less harmful alternatives or significant mitigation measures that the agency would otherwise have been required to consider if it

had complied with NEPA in the first instance. This standard for evaluating irreparable harm under NEPA ensures that NEPA's mandate is met and furthers the public interest in informed decisionmaking. Significantly, it also comports with the Council on Environmental Quality's regulations, which prohibit federal agencies from taking actions that would have adverse environmental impacts or limit the choice of reasonable alternatives. See 40 C.F.R. § 1506.1 (2009).

Further, a district court may properly decline to hold a trial-type evidentiary hearing to resolve factual disputes over the immediate and direct environmental harm that will result from a proposed action, if those facts are not material to its determination of injunctive relief. The critical issues at the injunction stage are limited to those made relevant by NEPA and the four-part test for injunctive relief. If a court determines that, due to the lack of required NEPA review, the proposed action raises significant factual disputes about the likely and serious harm to the environment, the court may exercise its discretion to enjoin the proposed action pending NEPA review, rather than assuming the agency's job and resolving the disputes itself. Similarly, if a court determines that allowing a proposed action to proceed may eliminate feasible alternatives that must be considered as part of the NEPA review process, the court should have the discretion to preserve the status quo until the agency

complies with NEPA, so that the outcome of the process is not skewed.

Finally, while the district courts have broad discretion to defer to submissions from a federal agency concerning the scope of injunctive relief, that deference is not automatic. Deference to an agency is warranted where the agency exercises its expertise through the proper administrative review process. Where it does not, the courts may defer to the opinion of an agency director or employee submitted in a declaration, as with any expert witness, based on an assessment of the demonstrated expertise of the declarant, the thoroughness of the analysis, and the persuasiveness of the reasoning.

ARGUMENT

I. IN FASHIONING INJUNCTIVE RELIEF UNDER NEPA, THE COURTS MUST CONSIDER ALL OF THE ENVIRONMENTAL HARMS THAT ARE LIKELY TO RESULT FROM SUBVERTING THE NEPA PROCESS.

A party seeking an injunction pursuant to NEPA must meet the normal requirements for injunctive relief, including demonstrating that "irreparable injury is *likely* in the absence of an injunction." *Winter,* 129 S. Ct. at 375. It is axiomatic, however, that in fashioning injunctive relief, courts must also consider the statute at issue, both in terms of whether Congress has limited the scope of the courts'

traditional equitable power to fashion relief, and in terms of the objectives of the statute and the harm it is intended to prevent. "The purpose and language of the statute under consideration . . . , not the bare fact of a statutory violation," compel the injunctive relief. *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 314 (1982). Then-Circuit Judge Breyer echoed this rule in the NEPA context, stating that, "the kinds of 'harms' that are relevant, and that may be 'irreparable,' will be different according to each statute's structure and purpose." *Sierra Club* v. *Marsh*, 872 F.2d 497, 502-03 (1st Cir. 1989).

Where statutes impose substantive requirements on environmental action, decisions by this Court have stressed that a claim for injunctive relief must be based on a showing of irreparable harm to the environment from a violation of those substantive requirements, not on a showing of irreparable harm to the statutory procedure itself. See *Romero-Barcelo*, 456 U.S. at 314 (Navy's failure to obtain discharge permit under Federal Water Pollution Control Act (FWPCA) was irreparable harm only to the extent it polluted the nation's waterways: "The integrity of the Nation's waterways, however, not the permit process, is the purpose of the FWPCA"); *Amoco Production Co.* v. *Village of Gambel*, 480 U.S. 531, 544 (1987) (purpose of Alaska National Interest Lands Conservation Act "is to protect Alaskan subsistence resources from unnecessary destruction," and, in granting injunction, Court of Appeals had "erroneously focused on the statutory procedure rather than on the

underlying substantive policy the process was designed to effect—preservation of subsistence resources").

Unlike the statutes at issue in *Romero-Barcelo* and *Amoco*, which impose substantive requirements on federal actions,[1] "NEPA imposes only procedural requirements to 'ensur[e] that the agency, in reaching its decision, will have available, and will carefully consider, detailed information concerning environmental impacts.'" *Winter*, 129 S. Ct. at 376 (citation omitted). NEPA thus manifests a critical concern "with preventing uninformed action," *Marsh* v. *Oregon Natural Resources Council*, 490 U.S. 360, 371 (1989), and seeks to ensure that the agency "will not act on incomplete information, only to regret its decision after it is too late to correct." *Id.*

NEPA's goals are realized through a set of "action-forcing" procedures, *Robertson* v. *Methow Valley Citizens Council*, 490 U.S. 332, 348 (1989), including preparation of an environmental impact statement (EIS), which ensures that the detailed

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[1] The FWPCA limits the discharge of pollutants except under specified conditions subject to permit. 33 U.S.C. § 1311. ANILCA requires that federal decisions to permit the use of public land must include reasonable steps to minimize adverse impacts on subsistence uses and resources, 16 U.S.C. § 3120, ensure that rural residents engaged in subsistence uses have access to resources on public land, *id.* at § 3121(a), permit appropriate use for subsistence purposes of snowmobiles, motorboats, *id.* at § 3121(b), etc. See also discussion in *Sierra Club*, 872 F.2d at 500-02.

environmental information considered by the agency, is available to a larger public audience that may also play a role in the decisionmaking process, and to other state and federal agencies from which a project proponent may need permits. *Id.* at 349. The NEPA requirement that agencies "study, develop, and describe appropriate alternatives to recommended courses of action," 42 U.S.C. § 4332(E), further ensures that each agency "takes into proper account all possible approaches to a particular project (including total abandonment of the project) which would alter the environmental impact and the cost-benefit balance." *Calvert Cliffs Coordinating Committee, Inc.* v. *United States Atomic Energy Commission*, 449 F.2d 1109, 1114 (D.C. Cir. 1971).

When a federal agency acts or proposes to act without having completed the mandated environmental review and without having prepared the detailed environmental statement, it violates the most basic tenet of NEPA. This is true even if the action would have been entirely legal after completion of environmental review, and even if the action ultimately causes no harm to the environment. "If environmental concerns are not interwoven into the fabric of agency planning, the 'action-forcing' characteristics of [NEPA] § 102(2)(C) would be lost." *Andrus* v. *Sierra Club*, 442 U.S. 347, 350-51 (1979).

In its most recent discussion of the standard for granting a preliminary injunction in the NEPA context, this Court acknowledged NEPA's focus on the decisionmaking process as the crucial mechanism for

advancing the broad congressional goals and the public's interest in ensuring that federal agencies consider environmental consequences *before* they act. While the Court ultimately did not reach the question of what constitutes irreparable harm under NEPA, it did state that "[p]art of the harm NEPA attempts to prevent in requiring an EIS is that, without one, there may be little if any information about prospective environmental harms and potential mitigating measures." *Winter,* 129 S. Ct. at 376. This recognition is critical to any analysis of what constitutes irreparable harm in the NEPA context.

In assessing irreparable harm under NEPA, the courts must therefore consider more than the direct physical harm to the environment from the proposed action, i.e., the "ground-disturbing" harm, such as the logging of timber, the damming of a river, or the commencement of mining. They must consider as well the environmental harm that results from the circumvention of the decisionmaking process. This includes the fact that the plaintiff "will have been deprived of the opportunity to participate in NEPA process at a time when such participation is required and is calculated to matter," *Save Strawberry Canyon* v. *Dep't of Energy*, 613 F. Supp. 2d 1177, 1189 (N.D. Cal. 2009), and the government decisionmaker will make an uninformed choice and may act when there is "little if any information about prospective environmental harms and potential mitigating measures." *Winter,* 129 S. Ct. at 376; see also *Marsh,* 490 U.S. at 371. "Thus, when a decision to which

NEPA obligations attach is made without the informed environmental consideration that NEPA requires, the harm that NEPA intends to prevent has been suffered." *Sierra Club,* 872 F.2d at 500.

These NEPA violations result in more than simply a procedural harm. The harm "at stake in a NEPA violation is a harm to the environment, not merely to a legalistic 'procedure.'" *Sierra Club,* 872 F.2d at 504. Permitting action to proceed without adequate environmental review both increases the likelihood of environmental harm and limits the possibility of the selection of other, potentially less environmentally harmful courses of action. After all, it is "far easier to influence an initial choice than to change a mind already made up." *Massachusetts* v. *Watt,* 716 F.2d 946, 952 (1st Cir. 1983) (Breyer, J.).

In exercising its equitable discretion to decide whether to enjoin further action pending the outcome of environmental review, the court must therefore consider and weigh the danger to the environment from proceeding without full environmental review. This, in turn, will depend on the nature of the proposed action and the extent of any environmental review already conducted. This weighing and balancing is part of the district court's inherent discretion in issuing injunctive relief. See *eBay,* 547 U.S. at 391. And where the district court has insufficient information to determine harm with some degree of certainty, it must have the discretion in equity to enjoin an action until more information

exists, i.e., until the agency fully and properly complies with NEPA.

In *Winter*, this Court noted that the existence of adequate information about the environmental consequences of a proposed action is a critical factor that the courts should consider in exercising their discretion to decide whether to enjoin an action. The Court explained that one reason it was appropriate to permit the Navy to proceed with its sonar training activity was that adequate information was available about the proposed interim action.

> [T]his is not a case in which the defendant is conducting a new type of activity with completely unknown effects on the environment . . . Here, in contrast, the plaintiffs are seeking to enjoin—or substantially restrict—training exercises that have been taking place in SOCAL for the last 40 years. And the latest series of exercises were not approved until after the defendant took a "hard look at environmental consequences."

Winter, 129 S. Ct. at 376 (citation omitted).

In contrast to *Winter*, where a proposed federal action is relatively new, is unstudied, has unknown consequences, or where the risks are highly disputed, there is a greater violation of the decisionmaking process which, in turn, results in a higher likelihood of harm to the environment. It is this harm that NEPA is intended to foreclose. Thus, a court exercising its discretion to enjoin action pending

required NEPA review may be faced with entirely new and novel questions that arise as technology develops. While the cutting down of a forest may present clear evidence of irreparable harm, other actions—the handling of nuclear waste, the employment of new technologies to reduce greenhouse gas emissions, the use of genetic engineering—are on the cutting edge of science. The district court must therefore exercise its discretion to assess the need for an injunction, not based solely on the known and demonstrated direct harms to the environment, but on the broader harms that arise when the government seeks to proceed with actions that push the limits of known technology, without first conducting environmental review to determine the full extent of the likely harms.

In addition to the increased risk to the environment from permitting the agency to proceed in the absence of full environmental review, each action is a link in a longer set of actions leading to an ultimate outcome. If a federal agency is permitted to proceed with certain actions pending completion of the environmental review, even if actions themselves do not cause direct harm to the environment, they can create bureaucratic momentum—the "bureaucratic steam roller"—which may skew the analysis toward the original non-NEPA compliant decision. "[A]s time goes on, it will become ever more difficult to undo an improper decision (a decision that, in the presence of adequate environmental information, might have come out differently)." *Sierra Club*, 872 F.2d at 503.

Once the agency embarks down a certain path, the court can require it to go back and prepare the required environmental review document, but the court cannot require it to change course. "Given the realities, the farther along the initially chosen path the agency has trod, the more likely it becomes that any later effort to bring about a new choice, simply by asking the agency administrator to read some new document, will prove an exercise in futility." *Sierra Club,* 872 F.2d at 503; see also *San Luis Valley Ecosystem Council* v. *U.S. Fish and Wildlife Service*, 657 F. Supp. 2d 1233, 1241-42 (D. Colo. 2009) (irreparable injury is not simply whatever "ground-disturbing activities are conducted in the relatively short interim before this action is decided"; it is the risk that the "bureaucratic momentum created by Defendants' activities will skew the analysis and decision-making of the [agency] toward its original, non-NEPA compliant access decision" (citation omitted)). NEPA's purposes are not served by environmental documents that are simply post hoc rationalizations for decisions already made.[2]

Thus, in assessing the scope of injunctive relief in the NEPA context, the courts must consider not only

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[2] See also Brief for the Federal Respondents Supporting Petitioners (U.S. Br.) at p. 31 (prior to completing environmental review, federal agency must show "that the actions it will take pending preparation of an EIS will not materially harm the environment and will leave open a reasonable range of alternatives for final agency decision").

the direct physical harm that will result from the proposed action, but also (1) the harm that results from permitting an action to proceed "with little if any information about prospective environmental harms and potential mitigating measures," *Winter*, 129 S. Ct. at 376, and (2) the harm of allowing the action to proceed where it will limit or even foreclose consideration of other, potentially less harmful alternatives, or significant mitigation measures that should be considered by the agency. Each of those harms is sufficient to justify a finding of likely "irreparable harm" that will support an injunction that prohibits the proposed action from advancing until the federal agency has fully complied with NEPA.

II. THE APPLICABLE CEQ GUIDELINES PROHIBIT ACTIONS THAT HAVE AN ADVERSE ENVIRONMENTAL IMPACT OR LIMIT THE CHOICE OF REASONABLE ALTERNATIVES.

The regulations promulgated by the Council for Environmental Quality (CEQ) to implement NEPA[3] make clear that the statute's essence is to require that "environmental information is available to public officials and citizens *before* decisions are made and *before* actions are taken." 40 C.F.R § 1500.1(b) (2009) (emphasis added). Therefore, until the NEPA process

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[3] This Court has recognized that the CEQ regulations are entitled to substantial deference. *Robertson*, 490 U.S. at 355; *Andrus*, 442 U.S. at 358.

is completed, the CEQ regulations, which are binding on all federal agencies, see *id.* at § 1500.3, impose strict limitations on federal action, prohibiting agency action that would have an adverse environmental impact or limit the choice of reasonable alternatives:

> (a) Until an agency issues a record of decision as provided in § 1505.2 . . . no action concerning the proposal shall be taken which would:
>
> (1) Have an adverse environmental impact; or
>
> (2) Limit the choice of reasonable alternatives.

40 C.F.R. § 1506.1(a) (2009).

The CEQ regulations therefore clarify the focus of environmental harm in the NEPA context. The purpose of NEPA is not merely to prevent irreparable harm to the environment as defined by the immediate known effects of a proposed action or set of actions; it is to prevent harm to the environment that results from permitting an agency to proceed with unexamined or insufficiently examined actions with unknown consequences, and which may limit the availability of reasonable alternatives. Pursuant to these CEQ regulations courts have properly enjoined further actions where the "options open to the [agency] would diminish, and at some point [its] consideration would become a meaningless formality." *National Audubon Society* v. *U.S. Dep't of the Navy*, 422 F.3d 174, 201 (4th Cir. 2005) (quoting *Arlington*

Coal. on Transp. v. *Volpe*, 458 F.2d 1323, 1333 (4th Cir. 1972).[4]

III. UNDER NEPA THE COURTS MAY EXERCISE THEIR DISCRETION TO ENJOIN PROPOSED ACTION WHEN THERE ARE SIGNIFICANT DISPUTES ABOUT SERIOUS ENVIRONMENTAL IMPACTS THAT WILL BE CONSIDERED AS PART OF THE NEPA REVIEW.

NEPA is intended to prevent federal agencies from acting without full consideration of the environmental impacts of their actions. See *Marsh*, 490 U.S. at 371. NEPA thus directs federal agencies to consider the potential environmental consequences of their actions "to the fullest extent possible," 42 U.S.C. § 4332, which is "a deliberate command that the duty NEPA imposes upon agencies . . . not be shunted aside in the bureaucratic shuffle." *Flint Ridge Dev. Co.* v. *Scenic Rivers Ass'n of Okla.*, 426 U.S. 776, 787 (1976). It would entirely subvert this purpose if a federal agency could ask a district court to resolve disputes about the environmental impacts of a proposed action before the agency has completed its consideration of those very same issues in a full and public NEPA process. Requiring district court

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[4] As the Fourth Circuit cautioned, however, this analysis does not require a court to enjoin all agency activity while the EIS is completed. *National Audubon Society*, 422 F.3d at 201-02 (modifying injunction to permit certain assessment, planning, and preliminary activities).

judges to assume this role violates the basic precepts of NEPA and administrative law.

The role of the courts in determining the scope of injunctive relief is different from the role of the federal agency in preparing an EIS. In the EIS process, the agency must consider all scientific evidence and make a determination as to the credibility and reliability of that evidence and the ultimate outcome of any scientific disputes. Thus, courts routinely defer to agency decisions taken after proper and full environmental review. See *Marsh*, 490 U.S. at 376-77; *Baltimore Gas & Electric* v. *Natural Resources Defense Council, Inc.*, 462 U.S. 87, 98-99 (1983) (decision made after the "careful consideration and disclosure required by NEPA").

In contrast, a court fashioning injunctive relief should not attempt to decide the ultimate scientific disputes that the agency must decide pursuant to NEPA. Rather, to the extent the court determines, after a review of the evidence submitted, that the harms from a proposed action are serious and a matter of significant dispute that will be the subject of subsequent NEPA review, the court need not and indeed, should not, attempt to resolve those disputes. To do so subverts the NEPA process, requiring the court to make a decision that was expressly left to the discretion of the expert agency after full public input and review. See 42 U.S.C. § 4332. Under these circumstances, the court has discretion to enjoin the proposed action pending agency review.

Similarly, if the court determines that the proposed action will eliminate or diminish the availability of reasonable alternatives, it has the discretion to enjoin the action, even if the action itself will not cause direct irreparable harm to the environment. See *Nat'l Audubon Society,* 422 F.3d at 201; see also discussion in Part II. An injunction preserving the status quo is critical in these circumstances because NEPA's alternatives analysis "is the heart of the environmental impact statement." 40 C.F.R. § 1502.14 (2009). It "requires federal agencies to consider whether they can carry out their proposed action in a less environmentally damaging manner and whether alternatives exist that make the action unnecessary." DANIEL R. MANDELKER, NEPA LAW AND LITIGATION § 9:18, at 9-45 (2d ed. 2009). The requirement to study, develop, and describe alternatives "both guides the substance of environmental decisionmaking and provides evidence that the mandated decisionmaking process has actually taken place." *Bob Marshall Alliance* v. *Hodel*, 852 F.2d 1223, 1228 (9th Cir. 1988). When an agency violates NEPA, a district court must retain the discretion to enjoin agency action pending full environmental review, lest the interim action effectively preordains the outcome.

Thus, applying the traditional rules for injunctive relief, a district court should have the discretion to determine, *inter alia*, that specific factual disputes presented by the parties concerning the direct harm from a proposed project or action

are not material to the court's determination of the scope of the NEPA injunction, and need not be decided by the court prior to issuing injunctive relief. Exercising discretion in this fashion is consistent with both the standard governing permanent injunctions and NEPA's purposes and textual mandate. See *Romero-Barcelo*, 456 U.S. at 312 (stating that the "essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each degree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it" (quoting *Hecht Co.* v. *Bowles*, 321 U.S. 321, 329 (1944))). Respect for this discretion ensures that district court judges are not forced to step into the shoes of federal agencies, acting as environmental experts, and that the status quo is preserved while the federal agency goes back to consider the environmental consequences of the action and makes a fully informed decision, untainted by litigation or interim resource commitments. Injunctions in this context thus serve to ensure that NEPA's statutory goals are achieved "to the fullest extent possible." 42 U.S.C. § 4332.

IV. IN FASHIONING INJUNCTIVE RELIEF UNDER NEPA THE COURTS SHOULD NOT AUTOMATICALLY DEFER TO THE CONCLUSIONS OF THE AGENCY THAT FAILED TO CONDUCT THE ENVIRONMENTAL REVIEW.

In deciding whether to issue an injunction, and the scope of that injunction, courts routinely give substantial weight to declarations submitted by

experts from federal agencies, based on the persuasiveness of those declarations and the particular context in which they arise.[5] This is appropriate. The United States, however, asks for something more. Relying on general principles of administrative law, the United States urges this Court to rule that the courts must defer automatically to the federal agency director's conclusions concerning what conditions the court should impose on interim actions pending the agency's compliance with NEPA. U.S. Br. at 35. In particular, the United States argues that "[j]ust as a court would have deferred to the agency's decision on an administrative remand, so too the district court should have deferred to the Director's submission." *Id.* at 37.

The United States' argument is precisely what this Court cautioned against in *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mutual Auto Insurance*, when it stated that "[e]xpert discretion is the lifeblood of the administrative process, but 'unless we make the requirements for administrative action strict and demanding, *expertise*, the strength of modern government, can become a monster which rules with no practical limits on its discretion.'" 463 U.S. 29, 48 (1983) (citation omitted).

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[5] See, e.g., *Winter*, 129 S. Ct. at 379 (court failed to give sufficient weight to evidence submitted by top Navy officers concerning harm that would result to Navy training efforts from the injunction).

Granting deference to a federal agency based only on its director's declarations would result in just such "a monster which rules with no practical limits on its discretion."

Courts are readily able to distinguish between those situations in which it is appropriate to defer to an agency and those in which it is not. Deference in the NEPA context is warranted only if the agency's decision, as reflected in the administrative record, is "fully informed and well-considered." *Save the Yaak Committee* v. *Block*, 840 F.2d 714, 717 (9th Cir. 1988). Deference is not warranted, however, where a court already has found that the agency failed to comply with NEPA and the Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706, in a way that affected the agency's ability to make a fully informed and objective decision.[6] Indeed, where a plaintiff has prevailed on the merits of its NEPA claim, the federal agency's views on the nature and scope of what actions should be taken pending environmental review are by definition post hoc and therefore not

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[6] In contrast to issues of environmental harm raised in the NEPA context, the deference afforded to agency declarations in *Winter* was based on deference to the opinion of military officials about the harm that the injunction would cause to military interests. *Winter*, 129 S. Ct. at 377 (courts "give great deference to the professional judgment of military authorities concerning the relative importance of a particular military interest" (citation omitted)). It was not deference that depended in any way on compliance with or expertise obtained through a public administrative procedure.

entitled to the type of deference courts generally give to agency decisions that are made in compliance with applicable procedures and supported by the administrative record.[7] Where an agency has violated NEPA by not adequately considering all of the environmental consequences of the proposed action, a court may choose to look with a critical eye at the agency's attempts to justify continuation of the action, in whole or in part, based on statements that the action is not likely to result in irreparable harm to the environment in the interim. See *Citizens Advisory Comm. on Private Prisons, Inc.* v. *U.S. Dep't of Justice*, 197 F. Supp. 2d 226, 251 (W.D. Pa. 2001) (agency attempt to cure NEPA violation "viewed with [some] suspicion"). This skepticism of an agency's views that are not the product of a full administrative proceeding, is appropriate where the agency's position skirted statutory procedures and "may have been developed hastily, or under special pressure, or without an adequate opportunity for presentation of conflicting views." *Federal Labor Relations Authority* v. *U.S. Dep't of Treasury*, 884 F.2d 1446, 1455 (D.C. Cir. 1989). Replacing agency deference based on an administrative procedure that includes public notice

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[7] "The purpose of confining judicial review to the administrative record is to ensure that agencies adequately evaluate their proposed course of action before they act and do not simply attempt to justify rash, uniformed actions through 'post hoc' rationalizations once they are aware they are being sued." *Highway J Citizens Group* v. *Mineta*, 349 F.3d 938, 958 (5th Cir 2003) (citations and internal quotations omitted).

and opportunity to be heard, with blind deference to declarations submitted for purpose of litigation, is unwarranted and inappropriate.

The cases on which the United States relies to justify deference in the face of agency failure to comply with procedural requirements do not involve NEPA and are factually and legally inapposite. In *Brock* v. *Pierce County*, the procedural breach at issue was the agency's failure to act to recover misused funds within a 120 day time period. 476 U.S. 253, 254-55 (1986). Relying on the principle that the public interest should not be prejudiced by the negligence of federal agents, this Court ruled that the agency did not lose its power to act through the procedural misstep. *Id.* at 260. *Barnhart* v. *Peabody Coal Co.* involved the failure of an agency to assign coal industry retirees to an operating company by a certain date for purposes of benefits. 537 U.S. 149, 152 (2003). The Court held that the failure to act within the statutory time limit did not divest the agency of its jurisdiction to act. *Id.* at 172.

In marked contrast here, the "procedural requirement" is the essence of the statute, and the public interest is in the information-gathering procedure itself. See *Sierra Club,* 872 F.2d at 500.[8] It

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[8] Again, as stated by then-Circuit Judge Breyer:

> Rather, the harm at stake is a harm to the *environment*, but the harm consists of the added *risk* to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis (with prior

(Continued on following page)

would be peculiar, to say the least, to give automatic deference to the statement of an agency official concerning the likelihood of environmental harm, when the agency violated its statutory duty to conduct an adequate review of that harm.

In sum, a court, exercising its judgment and discretion to determine whether an injunction should issue and the scope of that injunction, may find that declarations submitted by the agency are persuasive and therefore are entitled to substantial weight. Such a determination must be based, as with other expert witnesses, on the court's evaluation of the scientific expertise of the person presenting the evidence, the nature of the scientific review conducted, the strength and thoroughness of the analysis, and, where relevant, consideration of the agency's expertise and statutory mandates. What a court should not do, however, is afford the agency the type of deference to which its determinations and opinions are entitled only on administrative record review after that agency has complied with the Administrative Procedure Act. Deference of this latter type would be

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> public comment) of the likely effects of their decision upon the environment. NEPA's object is to minimize that risk, the risk of uninformed choice, a risk that arises in part from the practical fact that bureaucratic decisionmakers (when the law permits) are less likely to tear down a nearly completed project than a barely started project.

Sierra Club, 872 F.2d at 500-01.

an abrogation of the judiciary's authority and responsibility to fashion equitable relief.

CONCLUSION

The proper scope of injunctive relief depends on the nature of the statute at issue and the harm it seeks to avoid. NEPA does not mandate particular substantive environmental results. Rather, it promotes its environmental goals by "focusing Government and public attention on the environmental effects of proposed agency action. . . . By so focusing agency attention, NEPA ensures that the agency will not act on incomplete information, only to regret its decision after it is too late to correct." *Marsh*, 490 U.S. at 371.

Accordingly, injunctive relief to prevent the agency from proceeding with a proposed action pending environmental review may be appropriate, even where immediate harm to the environment from the proposed action is not absolutely certain to occur. In assessing harm, a court must consider environmental harm that is likely to result from violation of the critical decisionmaking processes mandated by NEPA—the fact that the proposed action is undertaken when "there may be little if any information about prospective environmental harms and potential mitigating measures," *Winter*, 129 S. Ct. at 376, as well as the fact that the action may eliminate reasonable alternatives that might be less

harmful to the environment and should be considered in the NEPA review process. 40 C.F.R. § 1506.1.

Thus, if NEPA is not to be merely a "paper tiger," see *Calvert Cliffs' Coordinating Comm.*, 449 F.2d at 1114, the courts must have the mandate to consider and the discretion to enjoin not only actions that have direct and known adverse impacts on the environment, but also those actions that subvert NEPA's procedural requirements, distort the outcome of the process, and increase the likelihood of serious, irreparable harm to the environment that cannot be addressed by after the fact environmental review.

Dated: April 5, 2010

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AMICUS CURIAE BRIEF

No. 09-475

In The
Supreme Court of the United States

MONSANTO COMPANY, et al.,

Petitioners,

v.

GEERTSON SEED FARMS, et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF FOR *AMICI CURIAE* UNION OF CONCERNED SCIENTISTS, CENTER FOR RESPONSIBLE GENETICS, DR. STEVEN R. RADOSEVICH, DR. PAUL E. ARRIOLA, DR. JOHN FAGAN, DR. E. ANN CLARK, DR. DON M. HUBER, AND CAROLINE COX IN SUPPORT OF GEERTSON RESPONDENTS

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INTEREST OF *AMICI*[1]

Amicus curiae Union of Concerned Scientists ("UCS"), a leading science-based non-profit working for a healthy environment and a safer world, combines independent scientific research and citizen action to develop innovative, practical solutions and secure responsible changes in government policy, corporate practices, and consumer choices. What began as a collaboration between students and faculty members at the Massachusetts Institute of Technology in 1969 is now an alliance of more than 250,000 scientists and citizens. A major interest of UCS's Food and Environment Program is to strengthen the regulatory system that applies to products of agricultural biotechnology.

Amicus curiae Council for Responsible Genetics ("CRG") is a national non-profit organization with offices in Cambridge, Massachusetts and New York, New York. CRG was founded in 1983 to represent the public interest and foster public debate about the social, ethical and environmental implications of genetic technologies. CRG is dedicated to examining the best science, interpreting the results, assessing the implications, communicating them to a general

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[1] Pursuant to Rule 37.6, counsel for *amici* state that no counsel for a party authored this brief in whole or in part, and that no person other than *amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Petitioners and respondent have filed a letter of consent with the Clerk of the Court.

audience and creating lasting policy reform. CRG has investigated and reported on the commercial claims made about genetically modified crops and transgenic animals introduced into the food supply. CRG has questioned the compatibility of herbicide resistant plants and insect resistant crops with sustainable agriculture. CRG believes that all uses of genetically modified crops should meet rigorous safety testing and follow procedures of democratic participation by public stakeholder groups. CRG publishes a magazine, GeneWatch, that regularly includes articles by experts in the field on issues related to genetically engineered food.

Amicus curiae Steven R. Radosevich, Ph.D., is an Emeritus Professor at Oregon State University. Dr. Radosevich is a faculty member of the Department of Forest Ecosystems and Society and also an Adjunct Professor in the Departments of Crop Science, Environmental Sciences, and Philosophy. Dr. Radosevich's areas of expertise include Invasive Plant Species, Forest Ecology and Sustainable Forestry. He wrote the only textbook on the Ecology of Weeds and Invasive Plants, now in its third edition (Radesovich et al. 2007), and has been researching herbicide resistance since 1970. He received his M.S. and Ph.D. from Oregon State University and his B.S. from Washington State University.

Amicus curiae Paul E. Arriola, Ph.D., is a Professor of Biology at Elmhurst College in Elmhurst, Illinois. Dr. Arriola's areas of expertise include the population genetics and ecology of invasive plant species, with recent work addressing the consequences of

the escape of engineered genes into wild/weedy plant populations. He received his Ph.D. in Botany (Plant Genetics) and B.S. in Biology from University of California, Riverside.

Amicus curiae John Fagan, Ph.D., is founder and Chief Scientific Officer of Global ID Group, which includes Genetic ID, a pioneer in the development of DNA tests to detect genetically modified organisms in food and agricultural products. Dr. Fagan formerly conducted biomedical research at the U.S. National Institutes of Health, studying molecular mechanisms of carcinogenesis. He holds a Ph.D. in Molecular Biology, Biochemistry, and Cell Biology from Cornell University.

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Amicus curiae Don M. Huber, Ph.D., is Professor Emeritus of Plant Pathology at Purdue University. Dr. Huber's agricultural research over the last fifty years has focused on the epidemiology and control of soilborne plant pathogens. He is internationally recognized for his expertise in herbicide-nutrient-disease interactions and cultural control of plant diseases. He received his Ph.D. from the Michigan State

University and his B.S. and M.S. from the University of Idaho.

Amicus curiae Rubens Onofre Nodari, Ph.D., is a Full Professor and Graduate Program Sub-Coordinator at Federal University Of Santa Catarina. Dr. Nodari's areas of expertise include Characterization and Conservation on Genetic Diversity, Plant Breeding and Risk Assessment in genetically modified crops. He received his M.S. from Federal University of Rio Grande do Sul and Ph.D. from the University of California at Davis.

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Amicus curiae Caroline Cox is Research Director at the Center for Environmental Health ("CEH"). Ms. Cox leads CEH's research on toxic exposures, identifying, analyzing and substantiating the scientific bases for CEH's work to eliminate threats to children and others exposed to dangerous chemicals in consumer products. She writes and speaks regularly as a national expert on the toxicity of and alternatives to pesticides. Ms. Cox has a M.S. in

entomology from Oregon State University and is a graduate of Swarthmore College.

SUMMARY OF ARGUMENT

Genetically modified – or transgenic – crops pose substantial risks of harm to the human environment. The two most significant risks in this case are (1) the spread of unwanted transgenes to surrounding fields and wild plant populations and (2) the proliferation of herbicide-resistant weeds.[2] Both events are likely, and when either occurs, the resulting harm is effectively irreversible.

The district court found that these environmental risks were not adequately evaluated before Federal Respondents deregulated the transgenic crop Roundup Ready Alfalfa ("RRA") and, accordingly, it ordered further environmental review. To give effect to its liability ruling, the court fashioned an interim remedy that undid the premature deregulation by prohibiting new RRA planting pending completion of the requisite environmental risk analysis. That remedy comports with the general directive of the Administrative Procedure Act that courts "set aside"

[2] Because genetically modified crops do not exist in nature and are developed on an accelerated time scale never before seen in human history, they also may carry risks to consumers, as discussed briefly below. This brief focuses, however, on the two most significant environmental risks that lie at the heart of this case.

unlawful agency action, thereby restoring the status quo ante. 5 U.S.C. § 706(2); *Bowen v. Mass.*, 487 U.S. 879, 911 (1988) (noting that "[i]t seems perfectly clear" that upon finding an agency action unlawful, district court has "authority to grant the complete relief authorized by § 706").

Whether the remedy here is styled as a simple vacatur of the unlawful deregulation decision or as an affirmative injunction, its entry by the court was proper. The scientific literature fully supports interim restoration of the pre-decisional "no planting" regime until a proper environmental review is completed. While the likelihood of cross-contamination or the emergence of glyphosate-resistant weeds in any specific instance may appear small, the history of transgenic crops in the United States attests to one inescapable fact – in the aggregate, the collective risks from widespread use of RRA add up to a near certainty of irreparable harm. The district court's order setting aside the RRA deregulation action until those risks are adequately studied was, therefore, entirely consistent with its statutory and equitable authority.

ARGUMENT

RRA is a transgenic form of alfalfa (*Medicago sativa* ssp. *sativa*). It consists of a standard agricultural line of alfalfa that has been genetically modified, or transformed, by the insertion into its

genome of a foreign gene that conveys resistance to the herbicide glyphosate. Glyphosate is the active ingredient in the Roundup line of herbicides marketed by Monsanto. The transformation process used to create herbicide resistant crops is unlike the slow, steady process of traditional plant breeding that humans have practiced for millennia. Modern genetic engineering results in new plant gene combinations that have never occurred in nature, with attendant new risks to consumers, farmers, and the environment. The widespread use of RRA will bring with it certain predictable, serious risks of irreparable harm to farmers and to the public.

I. THE GENETIC CONSTRUCT THAT MAKES RRA HERBICIDE RESISTANT DOES NOT OCCUR IN NATURE AND THE PROCESS BY WHICH IT WAS CREATED IS TOTALLY UNLIKE TRADITIONAL PLANT BREEDING.

A gene that scientists insert into another organism is called a "transgene," and organisms receiving the gene are "transgenic." The RRA genetic construct consists of fragments of DNA assembled together in the laboratory which do not occur together in nature. The main part of the RRA genetic construct – the coding region – consists of a gene from the soil bacterium Agrobacterium (*Agrobacterium tumefaciens*)[3] that

[3] U.S. patent #5633435

allows plants to grow even when treated with glyphosate. It is fused to gene fragments from petunia, pea, the laboratory model plant Arabidopsis, and the figwort mosaic virus.

The protein created by this RRA transgene does not affect potential yield.[4] It does not increase a plant's rate of growth, final size, or nutrient content. The new protein serves only one function – it enables the plant to survive glyphosate treatment.

To transform alfalfa as described above, researchers rely on the same soil bacterium, Agrobacterium, that is the source of the RRA transgene coding region. Agrobacterium is a naturally occurring pathogen that induces cancer-like tumors in plants. Unlike bacteria that infect people, Agrobacterium inserts its own genes into (that is, it "transforms") individual cells of the host plant. In the wild, Agrobacterium genes cause the transformed cells to grow and divide uncontrollably and to produce a form of sugar that only Agrobacterium is able to use.

A major development in plant molecular biology came about with the discoveries that scientists can (1) replace Agrobacterium's tumor genes with any other gene sequence without affecting Agrobacterium's

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[4] *See, e.g.*, Wendy Pline-Srnic Pest Manag. Sci. 61:225-234 (2005), at 228.

ability to insert these sequences into the host,[5] and (2) induce Agrobacterium to infect a broad array of plant species under laboratory conditions.[6,7,8,9,10] Following these discoveries, researchers began using Agrobacterium to transform plants with foreign genes in order to observe the effect these genes had on plant growth and development. Over the last two decades, scientists developed more sophisticated transformation methods that do not rely on Agrobacterium. These methods dominate genetics research today.

Three characteristics of the transformation process deserve emphasis. First, genetic engineering involving Agrobacterium and other transformation methods is a powerful technology that allows scientists, for the first time ever, to combine genetic

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[5] *See, e.g.*, A. Muller et al., *High meiotic stability of a foreign gene introduced into tobacco by Agrobacterium-mediated transformation*, 207 Mol. Gen Genet. 171 (1987).

[6] N. Bechtold et al., *In planta Agrobacterium mediated gene transfer by infiltration of adult* Arabidopsis thaliana *plants*, 316 CR Acad. Sci. Paris 1194 (1993).

[7] N. Bechtold and G. Pelletier, *In planta Agrobacterium-mediated transformation of adult* Arabidopsis thaliana *plants by vacuum infiltration*, 82 Methods Mol. Biol. 259 (1998).

[8] P. Chee et al., *Transformation of Soybean* (Glycine max) *by Infecting Germinating Seeds with* Agrobacterium tumefaciens. 91 Plant Physiol. 1212 (1989).

[9] J. Gould et al., *Transformation* of Zea mays L. *Using* Agrobacterium tumefaciens *and the Shoot Apex*, 95 Plant Physiol. 426 (1991).

[10] C. Loopstra et al., *Agrobacterium-mediated DNA transfer in sugar pine*, 15 Plant Mol. Biol. 1 (1990).

material from widely dissimilar and unrelated organisms – for example, bacterial genes with alfalfa genes or chicken genes with maize genes. In other words, scientists can produce combinations of genetic material that have never before occurred in nature.

Second, neither scientists nor the bacteria themselves can control where in the target plant genome the foreign gene will be inserted. Agrobacterium may insert its genes anywhere in native plant genes, thereby interrupting them or altering their function. One way to envision this process is to think of the genome as a book and of individual genes as the sentences that make up that book. Agrobacterium or scientists paste new sentences into the book randomly, without any regard for the words already there. In fact, researchers rely on this process when they want to interrupt plant genes at random to study the effects of the resulting damage.[11,12,13]

Third, the process whereby Agrobacterium or scientists insert genes into the host plant genome can be unpredictable. Genes may be inserted multiple times, in multiple locations, as intact genes or as gene

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[11] P. Krysan et al., *T-DNA as an Insertional Mutagen in Arabidopsis*, 11 Plant Cell 2283 (1999).

[12] M. Sussman et al., *The Arabidopsis Knockout Facility at the University of Wisconsin-Madison*, 124 Plant Physiol. 1465 (2000).

[13] J. Alonso et al., *Genome-Wide Insertional Mutagenesis of* Arabidopsis thaliana, 301 Science 653 (2003).

fragments.[14,15] Both academic researchers studying weeds[16] and researchers at Monsanto's own facilities working with Roundup Ready transgenic crops[17] have observed this phenomenon.

The new combinations of genetic material from unrelated organisms and the disruption of host genes during the transformation process present risks both to the environment and to human health. For consumers, in particular, changes in a crop's genome could increase the abundance of endogenous plant toxins or allergens, generate novel toxins, or decrease nutritional content.[18] For these reasons, plant transformation as practiced on RRA creates a new

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[14] M. Sussman et al., *The Arabidopsis Knockout Facility at the University of Wisconsin-Madison*, 124 Plant Physiol 1465, 1466 (2000).

[15] Salk Institute Genomic Analysis Laboratory Arabidopsis sequence indexed TDNA insertion project FAQ (http://signal.salk.edu/tdna_FAQs.html) (Last visited March 6, 2010) (reading, "[a]pproximately 50% of the lines contain a single insert [of foreign gene sequence], the other 50% of lines contain two or more inserts.")

[16] Id.

[17] B Palevitz, *DNA Surprise: Monsanto discovers extra sequences in Roundup Ready soybean*, 14 The Scientist 20 (2000).

[18] As a result, when assessing the safety of transgenic crops such as RRA (and other transgenic crops already on the market), it is not sufficient to evaluate only the safety of the individual protein produced by the transgene itself. Instead, the potential for harm from the disruption of native plant genes during the plant transformation process should be evaluated.

transgenic plant whose safety and impact on people are unpredictable.

It is important to note that the transformation process for genetically modified crops is totally unlike traditional plant breeding. The latter process involves identifying similar, related plants with useful traits and crossing these plants to produce offspring with the best characteristics of both parents. Traditional breeding methods are responsible for significant improvements in myriad agronomically important traits (such as yield and pest resistance) in many crops over the past century. For example, in the last twenty years, the period during which transgenic crops were introduced, traditional breeding provided all but three to four percent of the 28 percent increase in maize yield.[19]

II. RRA IS LIKELY TO CONTAMINATE NEIGHBORING ALFALFA CROPS AND WILD ALFALFA POPULATIONS, CAUSING SIGNIFICANT PERMANENT HARM.

There is substantial evidence of human-designed genes contaminating conventional crops and wild relatives. The two major avenues of contamination are (1) pollen flow and (2) human error. Existing scientific

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[19] D. Gurian-Sherman, *Failure to Yield*, Union of Concerned Scientists 1, 3 (2009), http://www.ucsusa.org/food_and_agriculture/science_and_impacts/science/failure-to-yield.html (Last visited March 12, 2010).

studies demonstrate that RRA transgene contamination of alfalfa fields and wild alfalfa populations is likely to occur, difficult to undo, and costly for conventional and organic farmers.

A. Frequently Documented Transgene Movement Into Conventional Crops And Wild Relatives Demonstrates The Potential For Irreparable Harm.

Recent surveys document over 120 instances of transgene contamination since 1996.[20] These incidents have had a substantial impact on farmers, grain elevator operators, academic researchers, and consumers.

Contamination incidents are not limited to a single crop or region. Maize, rice, canola, tomatoes, and other crops have all been contaminated by transgenes. Transgene flow to other crops has occurred through cross-pollination of adjacent crops and wild plant populations, and perhaps most often, by simple human error. In many cases, the contamination occurred despite all parties following company-recommended guidelines for the prevention of transgene

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[20] *See* GeneWatch UK and Greenpeace International, *GM Contamination Report 2005 – A review of cases of contamination, illegal planting and negative side effects of genetically modified organisms*, 1, 6 (2005), available at http://www.greenpeace.org/international/press/reports/gm-contamination-report (Last visited March 17, 2010); *and* GeneWatch UK and Greenpeace International, GM Contamination Register, available at http://www.gmcontaminationregister.org.

movement. It is likely that contamination incidents will continue at somewhat the same frequency.

Harms from transgene contamination vary by incident, but are often irreversible. When detected early enough, the harms consist largely of financial losses to farmers and seed companies. It is not uncommon, however, for contamination events to spread far beyond their initial scope before regulators detect them. In these cases, the impact is to a much broader swathe of the agricultural community than the guilty party can conceivably compensate. And the flow of transgenes into wild populations is effectively irreparable. The transgenes will continue to contaminate agriculture and the environment indefinitely.[21]

1. Widespread Contamination By Transgenic Starlink Maize Illustrates The Potential For Environmental Harm.

Aventis CropScience's release of StarLink maize is perhaps the best-known instance of transgenic crop contamination.[22] StarLink transgenic maize harbors a

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[21] *Reviewed in* S. Smyth et al., *Liabilities and economics of transgenic crops*, 20 Nature Biotechnology 537, 539 (2002).

[22] *See, e.g.*, N. Harl, R Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010); *and Biotech Corn Tainted Vast Amounts. Company's Report Expands Estimate*. Washington Post, March 18, (2001), summarized at Non-GM-farmers, http://www.non-gm-farmers com/news_print.asp?ID=1168 (Last visited March 16, 2010).

transgene expressing a toxic protein meant to kill insects. In the late 1990s, regulators at the U.S. Environmental Protection Agency ("EPA"), following the advice of leading U.S. food allergists, identified the version of the toxic protein in StarLink as having a heightened risk for triggering allergic reactions compared to other versions. Consequently, the agency approved StarLink only for animal feed.[23]

To effectuate regulatory restrictions, Aventis specified that the maize was not for human consumption or international trade[24] and placed contractual constraints on the use of StarLink maize not unlike those proposed by Monsanto to contain RRA.[25] Nevertheless, StarLink maize soon turned up in Taco Bell taco shells produced by Kraft Foods, prompting a massive recall.[26] Similar recalls occurred throughout the following months as more product contamination became clear.

It is not clear what the relative contributions of cross-pollination and inadvertent mixing of maize in

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[23] N. Harl, R. Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010), at 2.

[24] Id., at 5

[25] Id., at 5

[26] A. Pollock, *Kraft Recalls Taco Shells with Bioengineered Corn*, N.Y. Times, September 23 (2000), at C1, available at http://www.nytimes.com/2000/09/23/business/kraft-recalls-taco-shells-with-bioengineered-corn.html?pagewanted=all (Last visited March 16, 2010).

grain elevators had in the movement of StarLink maize into human food channels. As one account explained, "[m]any [grain elevator operators] were unaware that any [transgenic maize line] had less than full domestic approval. This makes it likely that some corn containing StarLink . . . inadvertently entered elevators in those regions where it was grown in 1999. It is also possible that corn harvested adjacent to fields of StarLink corn could have been cross-pollinated."[27]

What is clear, however, is that the StarLink contamination event was widespread and had significant impacts. *Half of Iowa's maize harvest tested as contaminated with StarLink*, making it unusable for human consumption or export. Nationwide, StarLink contaminated 4 percent of that year's maize crop.[28]

The costs of this contamination event are huge but difficult to calculate. Aventis compensated farmers growing StarLink maize and maize grown within 660 feet of StarLink fields. The larger costs to grain companies and elevator operators of being stuck with contaminated mixed-maize stocks, and of cleaning their elevators, fell on the government. The

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[27] N. Harl, R. Ginder, C. Hurburgh and Iowa Attorney General S. Moline, *The StarLink Situation*, available at http://www.biotech-info.net/0010star.PDF (Last visited March 16, 2010), at 6.

[28] *Biotech Corn Tainted Vast Amounts. Company's Report Expands Estimate*. Washington Post, March 18, 2001, summarized at http://www.non-gm-farmers.com/news_print.asp?ID=1168 (Last visited March 16, 2010).

U.S. Department of Agriculture ("USDA") paid up to $20 million from a disaster relief fund to compensate seed companies for StarLink-contaminated planting seed, which had to be destroyed to prevent growers from inadvertently growing StarLink-contaminated corn.[29] A 2004 class-action settlement resulted in a payment of $112 million to farmers whose crops were contaminated with StarLink maize.[30]

According to the National Corn Growers Association, "[t]he StarLink dilemma was an unfortunate situation for all corn growers, not just those who used the StarLink product. Corn prices dropped significantly as a result of the situation and that impacted the entire industry."[31] Furthermore, the settlement was "a step in the right direction, but *payments amount to little more than 'a drop in the bucket'* for farmers who experienced significant losses because of the StarLink disaster."[32] Taco Bell franchisees won

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[29] M. Kaufman, *The U.S. Will Buy Back Corn Seed; Firms to be Compensated for Batches Mixed With Biotech Variety*, Washington Post, March 8 (2001), archived at http://www.encyclopedia.com/doc/1P2-429720.html (Last visited March 16, 2010).

[30] *U.S Farmers to Get $112 Million for GE Starlink Corn Contamination*, GM WATCH daily, http://www.gmwatch.org. Available at http://www.organicconsumers.org/Corn/starlink.cfm (Last visited March 16, 2010).

[31] Id.

[32] Id. (emphasis added).

$60 million to compensate for lost business.[33] But the biggest cost, to the reputation of the U.S. agricultural industry, was far greater; in the years following the StarLink incident, maize exports to Japan declined 44 percent and similar declines occurred in other export markets. A final report by industry consultants estimated that the final cost of the contamination event could be in the 'billions of dollars.'[34]

2. Other Examples Of Pollen-Mediated Contamination Tell The Same Story.

Similar stories of other transgenic contamination in crops abound. In 2006, testing revealed that American rice had been extensively contaminated by an experimental herbicide-tolerant variety, known as LL601, that according to its developer, Bayer CropScience, had been discontinued in 2001. Investigators have never conclusively determined how and why LL601 genes showed up in commercial rice. But the impacts on rice producers were clear. They suffered $200 million in direct and indirect losses from rejected, LL601-contaminated grain shipments and a consequent drop in rice prices contributed to a total

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[33] *Taco Bell Franchisees to get $60 million*. Reuters, June 8, 2001, available at http://www.gmfoodnews.com/re080601.txt (Last visited March 16, 2010).

[34] S. Laidlaw, *Starlink fallout could cost billions*, Toronto Star, January 9, 2001, available at http://www.gmfoodnews.com/ts090101.txt (Last visited March 16, 2010).

economic loss estimated at between $741 million and $1.285 billion.[35]

Other reports have indicted pollen-mediated movement of herbicide resistance between canola fields,[36] from transgenic to wild populations of creeping bentgrass,[37] in wheat[38] and in corn.[39] John Fagan, founder of Fairfield, Iowa's Genetic ID, a company that screens for transgenic contamination, has explained that contamination happens "quite often."[40]

Notably, all parties involved often "had followed isolation rules, but the genes [carried in pollen grains]

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[35] Blue, E.N. (2007), "Risky Business," Neil Blue Consulting, for Greenpeace International, November 2007. http://www.greenpeace.org/international/press/reports/risky-business.

[36] M. Rieger et al., *Herbicide Resistance Between Commercial Canola Fields*. 296 Science 2386 (2002)

[37] L. Watrud et al., *Pollen-Mediated Movement of Creeping bentgrass – Evidence for landscape-level, pollen-mediated gene flow from genetically modified creeping bentgrass with CP4 EPSPS as a marker*. 101 Proc. Natl. Acad. Sci. 14533 (2004).

[38] *Genetically Altered Wheat Flagged – Thailand Detects Shipment Not Cleared For Commercial Sales*. Spokesman Review, October 14 (1999).

[39] I. Fürst, *Swiss soiled seed prompts tolerance question*, 17 Nature Biotechnology 629 (1999).

[40] K. Bett, *Mounting Evidence of Genetic Pollution from GE Crops – Growing Evidence of Widespread GMO Contamination*, Environmental Science and Technology, December 1 (1999), available at http://www.organicconsumers.org/ge/gepollution.cfm (Last visited March 17, 2010).

still moved into the [nontransgenic] foundation seed."[41] By 2001, farmers routinely found transgenes "in corn that has been grown organically for ten to fifteen years," according to Arran Stephens, president of Nature's Path Foods, an organic grocer. "There's no wall high enough to keep that stuff contained."[42]

3. Human Error Plays A Key And Inevitable Role In The Inadvertent Spread Of Transgenes.

Perhaps the greatest cause of transgene contamination is the "unscientific" phenomenon of simple human error. Fallible human beings mislabel bags, accidentally mix samples, take seeds from the wrong plant or put it in the wrong tube, confuse paperwork, miscommunicate with one another, and send seeds from the wrong stock. No one sets out to do these things, but they happen nonetheless.

Needless to say, no isolation practice, no agricultural precaution, and no reasonable degree of farmer diligence can protect against a seed company's simple mislabeling of transgenic seed as nontransgenic. In 1997, for example, Monsanto sold Roundup Ready canola that the government had not certified to be

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[41] S. Smyth et al., *Liabilities and economics of transgenic crops*, 20 Nature Biotechnology 537, 539 (2002).

[42] B. Lilliston, *Farmers Fight to Save Organic Crops*, The Progressive, September 2001, available at http://www.progressive.org/0901/lil0901.html (Last visited March 17, 2010).

safe. Upon realizing its mistake, Monsanto recalled 60,000 bags of seed, enough to plant 600,000 acres with the unapproved seed.[43]

The history is clear: Transgene contamination of conventional crops occurs often, despite farmers' efforts to comply with industry standards designed to protect against such events. It is expensive, particularly if not detected immediately. It can persist for years. And it harms exporting farmers' credibility beyond the immediate financial injury. Notwithstanding what seed companies like Monsanto say, the threshold of contamination that really matters is set internationally, as much by the marketplace as by foreign governments, not by any domestic standard of "reasonableness." As one affected farmer put it, "[t]he foreign buyers have flat out said they won't buy it. And I believe they won't."[44]

4. Transgene Flow Into Nearby Wild Populations Is Also Common And Irreparable.

Transgenes often contaminate local wild populations as well. When wild plants are sufficiently closely related to the transgenic crop, they can interbreed

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[43] The Western Producer, April 24, 1997.

[44] J. Gillis, *The Heartland Wrestles With Biotechnology*, Washington Post, April 22, 2003, at A01, available at http://www.biotech-info.net/heartland.html (Last visited March 18, 2010).

to form viable offspring. Transgene crops can also interbreed with populations of conventional crop that have escaped from the farm ("feral" populations). The resulting hybrid plants will inherit half of their genes (including the transgene) from the crop species plant parent and half of their genes from the wild relative.

Researchers have reported numerous cases of transgenic crops interbreeding with wild relatives.[45] One study identified 65 crops species as capable of interbreeding with wild relatives, with another 100 species believed to be able to hybridize.[46] The actual number of species capable of hybridizing may be in the tens of thousands or higher.[47]

In fact, gene flow from cultivated populations to wild relatives is well documented. It has been observed in sunflowers at multiple locations[48,49] and in

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[45] Reviewed in M. Bagavathiannan, and R. Van Acker (2009), *The Biology and Ecology of Feral Alfalfa* (Medicago sativa L.) *and Its Implications for Novel Trait Confinement in North America*, 28 Critical Reviews in Plant Sciences 69, 70 (2009)

[46] L. Rieseberg and J. Wendel, in *Hybrid Zones and the Evolutionary Process* (ed. R.G. Harrison, Oxford Univ. Press, New York) 70-109 (1993).

[47] C. Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806 (2003).

[48] D. Arias and L. Rieseberg, *Gene flow between cultivated and wild sunflowers* 89 Theor. Appl. Genet. 655 (1994).

[49] M. Ureta et al., *Gene flow among wild and cultivated sunflower,* Helianthus annuus *in Argentina*, 123 Agric. Ecosys. Environ. 343 (2008).

feral beet populations,[50] and the flow of multiple herbicide-resistance genes[51] and other natural genes[52] into feral canola populations is an ongoing problem. Triple herbicide-resistant canola has been detected in Canada, the result of crossing among three different single herbicide-tolerant varieties over several years.[53]

One effect of these crosses is that the transgene, originally intended to protect the crop species from an herbicide intended to kill weeds, may now protect some of the very weeds that the herbicide was designed to kill. "[W]hen novel genes spread to free-living plant populations, they have the potential to create or exacerbate weed problems."[54]

Transgene movement into wild populations harms farmers by making their investments in herbicide

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[50] J. Arnaud et al., *Evidence for gene flow via seed dispersal from crop to wild relatives in* Beta vulgaris *(Chenopodiaceae): consequences for the release of genetically modified crop species with weedy lineages*, 270 Proc. Biol Sci 1565 (2003).

[51] M. Aono et al., *Detection of feral transgenic oilseed rape with multiple-herbicide resistance in Japan*, 5 Environ. Biosafety Res 77 (2006).

[52] C. Devaux et al., *Modelling and estimating pollen movement in oilseed rape* (Brassica napus) *at the landscape scale using genetic markers*, 16 Mol. Ecol. 487 (2007).

[53] G. Steward, *A new breed of superweed*, The Toronto Globe and Mail, June 15, 2000, available at http://www.organicconsumers.org/ge/superweed.cfm

[54] A. Snow, *Transgenic crops – why gene flow matters*, 20 Nature Biotechnology 542, 542 (2002).

resistant crops useless, making their jobs more difficult, and making their products more costly to harvest. These harms ultimately are born not just by farmers but also by the population at large.

Wild relatives can cross-pollinate nontransgenic crops planted in their vicinity. "[Cross-pollination] from a crop to its wild relative is generally regarded as more difficult than from the wild relative to the crop."[55] Once a transgene gets into a wild population, this population will be a source of contamination to all fields within pollen's range for the indeterminate future.

As a consequence, the establishment of a transgene in a local population is effectively irreversible. Unlike contamination from a neighboring field of a transgenic crop, farmers cannot eliminate the source of contamination by plowing over the transgenic field. Wild plants often produce seeds that can lie dormant for years or even decades in so-called "seed banks" in the soil. Even if a farmer were willing and financially able to plow over every plant within miles of a plot, contaminated plants may still emerge from their seed banks for years to come. The impact of this contamination is that no farmer will be able to grow certifiably nontransgenic seeds from crops that can be cross-pollinated by contaminated wild relatives.

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[55] C. Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806, 809 (2003).

Although the individual chance of hybridization with a wild relative may be low in some cases, these numbers must be viewed in the context of the total number of chances that such an event will occur:

> [C]ross-pollination between white rice and red rice [its wild relative] is rare, probably occurring less than 1 percent of the time. But multiply that by millions and millions of rice plants, they say – and then start using [herbicide], which by killing conventional red rice will allow the [herbicide]-resistant weed to dominate – and within a few years, huge expanses of the South could be infested with [herbicide]-resistant red rice. '*Anyone who works with rice and red rice knows it*,' said Cynthia Sagers, a plant ecologist at the University of Arkansas. '*It's going to happen*'.[56]

B. RRA Transgene Contamination Of Adjacent Alfalfa Crops And Wild Populations Is Likely And Irreparable.

Petitioners' casual dismissal of these contamination risks for RRA are little more than wishful thinking. Their statistical argument is that because alfalfa is often grown as hay rather than to generate seed, the chance of transgene contamination is "2.5 in

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[56] R Weiss, *Biotech Rice Saga Yields Bushel of Questions for Feds – USDA Approval Shortcut Emerges as Issue*, Washington Post November 6, 2006, at 2, available at http://www.washingtonpost.com/wpdyn/content/article/2006/11/05/AR2006110501092.html (Last visited March 16, 2010) (emphasis added).

one million."[57] This calculation is based on the critical assumption that farmers will not let hay grow past 10 percent flowering before harvesting[58] and that "[h]ay crops are harvested . . . before the flowers open and produce the pollen necessary for cross-pollination."[59] This assumption, however, does not stand up to scrutiny.

According to the University of Wisconsin Extension, an academic outreach program that provides alfalfa farmers with scientific advice on their farming practices:

> The optimum yield and forage quality for milking dairy cows ranges from vegetative [absent all buds or flowers] to early bud on the first cutting to 10% flower on the second and third cuttings to full flower on a late-fall cutting. For animals with lower nutritional requirements, later stages [i.e., with more flowers] may be harvested.[60]

In other words, growing alfalfa for hay does not preclude the plants from flowering. On the contrary, agriculture experts advise farmers to allow some plants to grow "to full flower" in order to maximize yield.

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[57] Pet.App. 160a; Monsanto Petition for Certiorari, at 8.

[58] Pet.App. 128a-129a; Monsanto Petition for Certiorari, at 3.

[59] Monsanto Petition for Certiorari, at 4-5.

[60] D. Undersander et al., *Alfalfa germination and growth*, The learning store, University of Wisconsin Extension, available at http://www.learningstore.uwex.edu/pdf/A3681.PDF (Last visited March 15, 2010).

Petitioners' other key assumption – that alfalfa pollen grains are not dispersed by wind and are therefore unlikely to spread widely[61] – is equally suspect. Flowering RRA will release pollen that wild or domesticated honeybees or other wild insect pollinators may carry to adjacent fields. Researchers have documented occasional bee-mediated pollen transfer at distances of up to 4 kilometers (2.5 miles),[62] regular transfer at distances of 1 kilometer (0.6 miles), and over 90 percent cross pollination at 250 meters (0.15 miles, or 275 yards).[63] The fact that alfalfa is a bee-pollinated forage crop does not preclude it from contaminating adjacent fields. If adjacent nontransgenic fields and RRA fields flower at the same time, the transgenic pollen can easily contaminate adjacent fields.

Moreover, even if Petitioners' calculation of transgene contamination were accurate, the chance of transgene contamination is not negligible. Farmers will plant up to 22 million acres with RRA.[64] A mature stand easily contains five plants per square foot or

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[61] Pet.App 128a-129a; Monsanto Petition for Certiorari, at 3.

[62] L. Teuber et al., *Gene flow in alfalfa under honey bee* (Apis mellifera) *pollination*, In *Proceedings of the Joint Conference of the 39th North American Alfalfa Improvement Conference (NAAIC) and the 18th Trifolium Conference*, Quebec City, Quebec, Canada (2004).

[63] P. Amand et al., *Risk of alfalfa transgene dissemination and scale-dependent effects* 101 Theor. Appl. Genet. 107 (2000)

[64] Pet.App. 330a; Monsanto Petition for Certiotari, at 3.

218,000 per acre – that is, over 20 million plants on just 100 acres.[65] An event that occurs 2.5 times in a million ("almost a scientific impossibility" according to Petitioner)[66] becomes a fairly frequent occurrence when one has 22 million acres of chances.

The risk of transgene flow into wild, or "feral," alfalfa populations also is significant. Feral populations, as discussed above, create a number of problems for farmers. They readily cross with planted transgenic crops. They serve as a pollen source to contaminate nontransgenic crops, potentially over long distances. Most important, transgene contamination of feral populations is difficult if not impossible to undo.

RRA transgene is likely to move into feral alfalfa populations. Feral alfalfa populations occur along roadsides and other disturbed or unfarmed habitats throughout its planted range.[67,68,69,70] A survey

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[65] M. Rankin, *Alfalfa seeding rates: how much is too much*, University of Wisconsin Extension. http://www.uwex.edu/CES/crops/AlfSeedingRate.htm. Chart showing at least 8 plants per acre

[66] Monsanto Petition for Certiorari, at 17.

[67] F. Jenczewski et al., *Evidence for gene flow between wild and cultivated* Medicago sativa *(Leguminosae) based on allozyme markers and quantitative traits*. 86 American J. Bot. 677 (1999).

[68] S. Fitzpatrick et al., *Pollen-mediated gene flow in alfalfa: a three year summary of field research*. In: *Proceedings of 2003 Central Alfalfa Improvement Conference* (2003), available at http://www.foragegenetics.com/News.asp (Last visited March 18, 2010).

sponsored by Monsanto found feral alfalfa at more than 20 percent of almost 1,000 sites surveyed in five states and concluded that "[t]he proximity of feral populations to cultivated alfalfa suggests that gene flow will occur between these populations."[71] An independent academic researcher studying feral alfalfa similarly concluded that "[h]igh ferality potential makes gene flow even more probable."[72] Yet a third group listed alfalfa as a "Moderate Risk Crop" in terms of transgene flow to wild relatives, noting "if genes for herbicide tolerance were engineered into [alfalfa] crop populations they would probably

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[69] D. Kendrick et al., *Biogeographic survey of feral alfalfa populations in the U.S. during 2001 and 2002 as a component of an ecological risk assessment of Roundup Ready Alfalfa*, In: *Proceedings of North Central Weed Science Society Meeting*, UT, USA (2005), available at http.//www a-c-s.confex.com/crops/2005am/techprogram/P7242.HTM (Last visited March 18, 2010).

[70] M Bagavathiannan et al , *Feral nature of alfalfa: what role they could play in transgenic trait movement?* In: *Proceedings of Manitoba Agronomists' Conference*, The University of Manitoba, Winnipeg, MB, Canada (2006), available at http.//www umanitoba.ca/afs/agronomists_conf/proceedings/2006/bagavathiannan_feral_nature_of_alfalfa.pdf (Last visited March 18, 2010).

[71] Supra n.69.

[72] M. Bagavathiannan, and R. Van Acker (2009), *The Biology and Ecology of Feral Alfalfa* (Medicago sativa L.) *and Its Implications for Novel Trait Confinement in North America*, 28 Critical Reviews in Plant Sciences 69, 81 (2009).

introgress [move]" into their feral relatives' populations.[73]

RRA transgene contamination is likely to harm adjacent farmers in three ways. First, if the farmer intended to harvest nontransgenic seed from that crop (for example, to maintain nontransgenic seed stocks for the following planting season), the seed and any hay grown from this seed will be irreparably contaminated with the transgene.

Second, even if farmers harvest the adjacent contaminated crops for hay without allowing the seeds harboring the transgenes to mature, a screen for transgenic contamination of the type used by, for example, European crop regulators or RRA-sensitive alfalfa buyers will detect the transgene and destroy the crop's nontransgenic value.

Third, if a transgene contamination event occurs, it is likely to go undetected for some period of time. If so, the contamination is likely to spread in later generations as the transgene is planted in fields commingled with nontransgenic alfalfa, much as it did in StarLink maize and LL601 rice contamination events. By the time a foreign regulator or buyer detects the contamination, the scale of the harm may be prohibitively large.

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[73] C Stewart Jr., et al., *Transgene Introgression from Genetically Modified Crops to their Wild Relatives*, 4 Nature Reviews Genetics 806, 811 (2003).

III. RRA WILL HASTEN THE EMERGENCE OF GLYPHOSATE-RESISTANT WEEDS.

Deregulation of RRA will likely exacerbate a rapidly growing threat to U.S. agriculture: the emergence of glyphosate-resistant ("GR") weed populations on millions of acres of cropland, described by a leading weed scientist as "a threat to global food production."[74]

A. Selection Pressure Causes The Emergence Of Herbicide-Resistant Weeds.

Due to error in genome replication, a small amount of genetic variation is introduced with every new generation of a given organism. Most of these mutations are harmful or of no consequence to the individuals inheriting them. Occasionally, however, errors in DNA replication bring about changes that are beneficial. Usually these benefits only manifest in very limited circumstances. But under those circumstances, individuals harboring these beneficial heritable changes will rapidly out-compete others of their species. Such circumstances are said to "select" for the beneficial variant.

Glyphosate use selects for GR weeds, that is, it creates circumstances where, if a genetic variation conferring resistance to glyphosate does develop,

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[74] S. Powles, *Gene amplification delivers glyphosate-resistant weed evolution*, Commentary, Proc. Natl. Acad. Sci. 107:955-56.

plants harboring the genetic variation will quickly out-compete other weeds, and the once-rare variant will become common.

Many farmers have embraced Round Ready ("RR") technology, which relies on the ability of glyphosate to kill weeds.[75] RR soybeans grow on 92 percent of the land cultivated for soy.[76] The figures are similar for other crops – 90 percent for RR cotton,[77] 60 percent for RR maize,[78] and 75 percent for RR canola.[79] Other farming nations that allow transgenic crops have similar adoption rates.[80] If the USDA approves RRA for general use, it is likely that farmers will adopt it on a large scale.

The EPA shows that agricultural use of glyphosate has risen dramatically since RR crops were introduced in 1996, increasing 140 percent from just 1997 to 2001, when it became the most widely used

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[75] A. Cerdeira and S. Duke, *The Current Status and Environmental Impacts of Glyphosate-Resistant Crops: A Review*, 35 J. Environ. Qual. 1633, 1636 (2006)

[76] C. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years*, The Organic Center, Nov. 2009, Suppl. Tables 2-4. http://www.organic-center.org/sciencepest.php?action=view&report_ID=159.

[77] Id.

[78] Id.

[79] L. Gianessi, *Economic and herbicide use impacts of glyphosate-resistant crops*, 61 Pest Manag. Sci. 241 (2005).

[80] A. Cerdeira and S. Duke, *The Current Status and Environmental Impacts of Glyphosate-Resistant Crops: A Review*, 35 J. Environ Qual. 1633, 1636 (2006).

herbicide in the U.S.[81] And its use has doubled again since that time to reach 135 million pounds acid equivalents.[82] USDA pesticide usage data reveal a similar trend. Since 1996, the intensity of glyphosate use (pounds/acre/year) has doubled on soybeans (2006) and tripled on cotton (2007).[83]

Glyphosate is less environmentally harmful or toxic than many alternative herbicides.[84] As it is no longer under patent protection,[85] glyphosate's "cost has dropped dramatically."[86] Because of its broad activity and low environmental impact, glyphosate "is an ideal herbicide for use preplant, in fallow fields, and for spot or directed use to control an extensive

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[81] Environmental Protection Agency, *Pesticides Industry Sales and Usage: 2000 and 2001 Market Estimates*, Table 3.6 (2004).

[82] Center for Food Safety, *Comments on EPA's Registration Review of Glyphosate*, Docket No. EPA-HQ-OPP-2009-0361 (2009), Figure 1, http://www regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a28745.

[83] Supra n. 76, Fig. 1.1, Table 4.1.

[84] F. Fishel et al , *Herbicides: How Toxic Are They?* University of Florida IFAS Extension document PI-133, at 3 (2009) accessible at http://www.edis.ifas.ufl.edu/pi170 (Last visited March 7, 2010).

[85] Monsanto's patent on the glyphosate molecule expired in September, 2000.

[86] S. Duke and S. Powles, *Glyphosate: a once-in-a-century herbicide*, 64 Pest Manag. Sci. 319, 319 (2008).

range of annual and perennial weeds."[87] It facilitates no-till farming, a practice that prevents erosion and reduces agricultural fossil fuel use.

All of these traditional uses of glyphosate are being put at risk by weed resistance due to the excessive "post-emergence" use of glyphosate with RR crop systems. Good agricultural practices recommend that farmers alternate the type of herbicide that they use by, for example, "burning down" their fields (*i.e.*, treating them with herbicide to clear all weeds in anticipation of planting a crop or to clear a field after harvest) with an herbicide other than glyphosate.[88] In practice, farmers often rely on glyphosate exclusively.[89] Monsanto has encouraged excessive use by wrongly assuring farmers that Roundup-only weed control with RR crops would not lead to weed resistance.[90]

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[87] S. Powles et al., *Evolved resistance to Glyphosate in rigid ryegrass* (Lolium rigidum) *in Australia*, 46 Weed Science 604, 604 (1998).

[88] S. Powles, *Evolved glyphosate-resistant weeds around the world: lessons to be learnt*, 64 Pest Manag Sci 360 (2008).

[89] USDA-NASS, *Agricultural chemical use database* (2008), Upland Cotton 2007 Report, http://www.pestmanagement.info/nass/app_usage.cfm (Last visited March 18, 2010).

[90] B. Hartzler, *Two for the price of one*, Iowa State University, Dec. 17, 2004. Available at http://www.weeds.iastate.edu/mgmt/2004/twoforone.shtml.

A recent survey[91] reports that 18 weed species have developed glyphosate resistance in at least 52 U.S. populations and 40 more worldwide. The survey reveals millions of acres of U.S. cropland infested with 10 resistant weeds species, with the majority expanding in scope.[92] For example, GR Palmer amaranth (pigweed), first reported in one Georgia county in 2004, now infests several million acres in nine southern states, an extremely rapid spread that shows no signs of slowing.[93] Impacts for cotton farmers are severe as infestations can reduce yield by 50 percent[94,95] and have resulted in the abandonment of thousands of acres of cotton land.[96]

Since its discovery in Delaware in 2000, GR horseweed, which can reduce yields by 40-70 percent,

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[91] Herbicide-resistant weeds, http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12 (Last visited March 31, 2010).

[92] Id.

[93] S. Culpepper and J. Kichler, *University of Georgia Programs for Controlling Glyphosate-Resistant Palmer Amaranth in 2009 Cotton*, University of Georgia Cooperative Extension, April 2009, http://mulch.cropsoil.uga.edu/weedsci/HomepageFiles/Palmer2009.pdf.

[94] A. Culpepper et al., *Glyphosate-resistant Palmer amaranth* (Amaranthus palmeri) *confirmed in Georgia*. 54 Weed Science 620 (2006).

[95] T. Gaines et al., *Gene amplification confers glyphosate resistance in* Amaranthus palmeri, 107 Proc. Natl. Acad. Sci. USA. 1029 (2010).

[96] E. Robinson, *Designing the perfect weed – Palmer amaranth*, Delta Farm Press, Dec. 24, 2008, http://deltafarmpress.com/cotton/palmer-amaranth-1226/.

has infested up to 3.3 million acres in 16 states of the East, South, and Midwest.[97]

GR giant ragweed, infesting six Midwestern states and Arkansas and Tennessee, is a particular problem in soybeans, where just three to four plants per square yard can reduce yields by as much as 70 percent.[98]

Weed populations with multiple resistances to glyphosate and other herbicides are also on the rise, with six of eight identified since 2006.[99] Multiple-herbicide-resistant weeds reduce farmers' weed control options, cost more to manage, and in some cases may mean literally 'uncontrollable' weeds.

Researchers point to a clear cause for this resistance: "[t]he widespread adoption of glyphosate-tolerant (GT) crops, and subsequent glyphosate use, on a significant portion of the available agronomic cropland has provided a strong selection pressure for weeds that are not controlled by glyphosate."[100]

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[97] F. Laws, *Glyphosate-resistant weeds more burden to growers' pocketbooks*, Delta Farm Press, Nov. 27, 2006, http://deltafarmpress.com/news/061127-glyphosate-weeds/.

[98] B. Johnson & M. Loux, *Glyphosate-resistant giant ragweed confirmed in Indiana, Ohio*, Purdue University press release, Dec. 21, 2006.

[99] Supra n.91.

[100] T. Webster and L. Sosnoskie, *Loss of Glyphosate Efficacy: A Changing Weed Spectrum in Georgia Cotton*. 58 Weed Science 73 (2010).

The solution researchers advocate is not the abolition of RR crop use. Quite the contrary, scientists argue for increased oversight so that glyphosate may be used for generations to come:

> We are convinced that the unique features of glyphosate vitally necessitate its preservation for future harvests. Allowing glyphosate-resistant weeds to evolve unchecked will have huge adverse effects on the future of weed management worldwide. We hope that actions can be galvanized to save the world's greatest herbicide for future generations and future harvests.[101]

B. Unregulated Adoption Of RRA Will Have A Disproportionate Impact On The Selection For Glyphosate-Resistant Weeds.

Unregulated RRA adoption will increase the selection pressure for glyphosate resistance in weeds in a few important ways. Contrary to Petitioners' claims, at present farmers often use little or no herbicide when growing alfalfa, in sharp contrast to herbicide-heavy crops like maize, cotton and soybeans.[102,103]

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[101] S. Duke and S. Powles, *Editorial – Glyphosate-Resistant Weeds and Crops*, 64 Pest Manag. Sci. 317 (2008).

[102] Decl. of Charles M. Benbrook in Supp. of Pls.' Mot. For Summ J., Case 3:06-cv-01075-CRB, at 4.

[103] USDA (1999), "Agricultural Chemical Usage: 1998 Field Crops Summary," USDA's National Agricultural Statistics Service,

(Continued on following page)

Many farmers currently using no herbicide on alfalfa may adopt glyphosate with RRA, not in place of other herbicides but in place of companion cropping or other non-chemical means of weed control that do not select for glyphosate resistance. Based on EPA label rates, USDA determined that the maximum legally permissible amount of glyphosate that could be applied to RRA alone, given 90 percent adoption nationwide, was 142,761,960 pounds per year,[104] approximately the amount of glyphosate now used in all of American agriculture.[105] While alfalfa farmers would be unlikely to use so much, tens of millions of pounds of glyphosate could well be applied, with rates inevitably rising each year as resistant weeds proliferate, like they have for soybeans, cotton, and corn.

Another major risk from the unregulated adoption of RRA is the impact that it will have in the context of farmers' crop rotation strategies. "One of the most important ways to slow the development of resistance is to sequentially use different herbicides ... when different crops follow one another, are rotated, in a field over time."[106] In its 2004 petition for

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May 1999, p. 9. Just 7% of alfalfa hay acres were treated with herbicides in 1998, the latest reliable data available.

[104] USDA APHIS, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status. Draft Environmental Impact Statement, Nov. 2009, Appendix N at N17-N18.

[105] Supra n.82.

[106] Decl. of Doug Gurian-Sherman, For Perm. Inj., Case 3:06-cv-01075-CRB, at 4.

nonregulated status, Monsanto identifies corn as a major rotation crop with alfalfa, and argues that low RR corn adoption (7 percent in 2002) lessens resistant weed concerns.[107] With 60 percent rather than 7 percent of America's most widely grown crop now RR, many more farmers would rely on glyphosate exclusively for weed control rather than alternating herbicides as they alternate crops. This change will create an unbroken, steady selection pressure for glyphosate resistance. The impact of this change will far exceed the simple quantitative increase in glyphosate applied.[108]

C. Weed Resistance Constitutes Irreparable Harm.

Five main points emerge from the facts in this section. First, even though genomic variants conveying glyphosate resistance are very rare, it is an observed fact that they emerge over time. The more heavily that U.S. farmers rely on glyphosate, the stronger the selection pressure will be to encourage the spread of GR weeds once they emerge. This selection pressure will disproportionately increase if RRA is approved for general use.

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[107] Monsanto & Forage Genetics, Petition for Determination of Nonregulated Status. Roundup Ready Alfalfa (Medicago sativa L.). Events J101 and J163, April 16, 2004, pp. 302-303.

[108] Decl. of Doug Gurian-Sherman, For Perm. Inj., Case 3:06-cv-01075-CRB, at 5.

Second, the widespread emergence of GR weeds both reduces the efficacy of glyphosate and imposes substantial costs on farmers and U.S. agriculture in the form of reduced yields, increased production costs, greater soil erosion from increased weed tillage, and increased health and environmental harms associated with greater pesticide use.

Third, the emergence of GR weeds is preventable with appropriate agricultural practices. Specifically, scientifically-based stewardship regulations requiring that farmers diversify their weed control programs could substantially increase glyphosate's useful lifespan.

Fourth, although the emergence of GR weeds is preventable, the spread of glyphosate resistance over the course of a few generations within weed populations cannot be reversed once it has occurred.

Fifth, the parties suffering the greatest harm from GR weeds are the American farmer and, ultimately, the American consumer. Farmers rely on glyphosate because it is cheap, off patent, easy to apply, less harmful than most alternatives, and particularly conducive to no-till farming. Consequently, they can reduce their costs and pass some of these savings on to consumers. Because Petitioners no longer hold the exclusive patent to glyphosate, and their patents for many prominent RR crops are maturing, they have little incentive to protect the long-term efficacy of this herbicide.

In sum, the widespread adoption of RRA will substantially increase the rate at which resistant weeds emerge. It is extremely likely that these resistant weeds will emerge without a policy born of USDA Animal Plant Health Inspection Service's serious consideration of the risks. Once GR weeds emerge, their harm will be irreparable. Ultimately, American farmers and consumers will bear the burden from the loss of this useful agricultural tool.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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April 5, 2010

AMICUS CURIAE BRIEF

14

No. 09-475

Supreme Court, U.S.
FILED
MAR 8 - 2010
OFFICE OF THE CLERK

B258352

IN THE

Supreme Court of the United States

MONSANTO CO., ET AL.,

Petitioners,

v.

GEERTSON SEED FARMS, ET AL.,

Respondents.

On Writ of Certiorari
To the United States Court of Appeals
For the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

Amici curiae address only the following questions:

(i) Did the Ninth Circuit err in holding that a district court may enter an injunction sought to remedy a NEPA violation without conducting an evidentiary hearing sought by a party to resolve genuinely disputed facts about the likelihood of irreparable harm?

(ii) Did the Ninth Circuit err when it affirmed a blanket, nationwide injunction to remedy a purely procedural violation based only on a remote possibility of irreparable harm?

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BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a non-profit, public interest law and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. WLF regularly publishes monographs and other publications on these and related topics. In particular, WLF has regularly appeared before this and numerous other federal and state courts to urge adherence to traditional restraints on the granting of injunctive relief, including the requirement that an injunction should not issue unless the party seeking it can prove a likelihood of irreparable harm in its absence. *See, e.g., Winter v. NRDC*, 129 S. Ct. 365 (2008); *Nat'l Audobon Soc'y v. Dep't of Navy*, 422 F.3d 174 (4th Cir. 2005).

Allied Educational Foundation (AEF) is a non-profit, charitable and educational foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study and has appeared as *amicus curiae* in this Court on a number of occasions.

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[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation and submission of this brief.

Amici agree with Petitioners that the appeals court's decision below, if allowed to stand, threatens to make nationwide injunctions in NEPA cases virtually automatic in the Ninth Circuit, despite the absence of any language in NEPA suggesting that Congress has excused federal courts from complying with the traditional safeguards for equitable relief. *Amici* believe that injunctive relief is especially inappropriate where, as here, the trial court refuses to conduct an evidentiary hearing to resolve highly contested issues of material fact as to the likelihood of irreparable harm.

Amici have no direct interest, financial or otherwise, in the outcome of this case. *Amici* submit this brief solely to further the public interest in safeguarding the longstanding rule that an injunction is a matter of equitable discretion that does not result automatically from success on the merits. All parties have consented to the filing of this brief, and letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

This case raises important issues about the Ninth Circuit's standard for granting an injunction as a remedy under the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-4370, given that circuit's affirmance of the district court's virtual presumption of irreparable harm requiring an injunction in all "run of the mill" NEPA cases.

Petitioner Monsanto Co. (Monsanto) is a leading agricultural company that manufactures the world's best-selling herbicide, Roundup. Monsanto also develops and licenses leading seed brands for large-acre and small-

acre crops, including alfalfa. In the 1990s, Monsanto began developing "Roundup Ready alfalfa," a genetically modified variety of alfalfa that is resistant to Roundup. Petitioner Forage Genetics International (FGI) is the sole Monsanto-licensed producer of Roundup Ready alfalfa seed.

Monsanto and FGI petitioned the United States Department of Agriculture (USDA) to deregulate Roundup Ready alfalfa. After 297 field trials conducted over eight years of testing, the USDA, acting through the Animal and Plant Health Inspection Service (APHIS), determined that Roundup Ready alfalfa did not pose a plant pest risk. Pursuant to NEPA, APHIS prepared an Environmental Assessment (EA) and received hundreds of public comments on the deregulation petition. Having determined that deregulation would not significantly impact the environment, APHIS issued a Finding of No Significant Impact (FONSI) and approved the deregulation of Roundup Ready alfalfa, thereby allowing it to be sold and planted commercially.

Eight months later, Respondents Geertson Seed Farms and Trask Family Seeds, together with various environmental groups, sued the USDA to challenge its decision to deregulate, contending that APHIS violated NEPA by failing to take the necessary "hard look" at environmental consequences. Concluding that APHIS had failed to explain adequately why the possibility of cross-pollination of conventional and organic alfalfa by Roundup Ready alfalfa was not a significantly harmful environmental impact, the U.S. District Court for the Northern District of California granted Respondents' motion for summary judgment on their NEPA claim. Pet. App. 35a-45a, 51a-52a. The district court's holding

emphasized the need to prevent cross-pollination of conventional and organic alfalfa by imposing geographic isolation distances for Roundup Ready alfalfa seed crops. *Id.* at 36a, 52a.

At the remedies phase, the district court ordered APHIS to prepare an Environmental Impact Statement (EIS). Respondents sought a preliminary and permanent injunctive relief, but APHIS submitted a proposed order designed to prevent any significant likelihood of cross-pollination during the agency's preparation of its EIS. *Id.* at 185a-86a. Petitioners Monsanto and FGI intervened to support APHIS's proposed measures, which were far more stringent than the voluntary stewardship practices previously observed by farmers during field testing. *Id.* at 140a, 162a-63a. Claiming irreparable harm in the absence of injunctive relief, Respondents rejected APHIS's proposal and demanded a nationwide injunction that would completely ban any further use of Roundup Ready alfalfa pending APHIS's completion of the EIS. *Id.* at 13a, 64a. In its March 12, 2007 preliminary injunction order, the district court held that "absent unusual circumstances," an injunction should automatically issue following a violation of NEPA's procedural requirements. *Id.* at 55a. Because "[n]either the intervenors nor the government h[ad] identified any 'unusual circumstances,'" the court issued a nationwide injunction against all planting of Roundup Ready alfalfa from March 31, 2007 until the completion of the EIS. *Id.* at 56a-58a. In doing so, the district court failed to apply the traditional four-factor test required for an injunction, and failed to identify any likelihood of irreparable harm associated with Roundup Ready alfalfa.

On the issue of permanent injunctive relief, the

district court invited the government and Petitioners to "submit additional evidence or a further memorandum" and allowed Respondents to respond to those submissions. *Id.* at 58a. In their evidentiary submissions, the parties disputed nearly every factual issue relevant to whether irreparable harm to Respondents would result from the continued use of Roundup Ready alfalfa. Desiring to cross examine Respondents' experts on the scientific basis for their conclusions (and to afford their own experts an opportunity to testify), Petitioners requested a full evidentiary hearing to resolve all disputed issues of fact. The district court refused, stating that "it isn't my job" to "look and analyze and try to figure out, does this have an environmental impact or doesn't it." *Id.* at 68a, 417a. Without analyzing Petitioners' proposed expert testimony or allowing any cross-examination of Respondents' contrary assertions, the district court summarily concluded that "I should stop things in place until the Government has discharged its duty given to it by the right of Congress of the United States." *Id.* at 417a.

In its permanent injunction order, the district court acknowledged that "intervenors have requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed," but reiterated its refusal to "engage in precisely the same inquiry" that "APHIS failed to do and must do in an EIS." *Id.* at 67a-68a. Announcing that "more liberal standards for granting an injunction" apply in "run of the mill" NEPA cases, the district court entered a blanket nationwide injunction against any further planting of Roundup Ready alfalfa, but failed to

determine whether irreparable harm would be likely under the government's proposed mitigation measures. *Id.* at 60a-79a.

APHIS and Petitioners appealed. A divided panel of the U.S. Court of Appeals for the Ninth Circuit affirmed the district court's permanent injunction order. In an amended opinion, the appeals court never discussed this Court's holding in *Winter v. NRDC*, 129 S. Ct. 365, 375 (2008), which requires a showing of likely irreparable harm before an injunction can issue in a NEPA action. Rather, the appeals court effectively endorsed the district court's presumption of harm in all "run of the mill" NEPA cases. *Id.* at 13a.

While acknowledging that "generally, a district court should hold an evidentiary hearing" absent waiver by the adverse party, the Ninth Circuit did not require the district court to adjudicate the disputed issues of material fact on the likelihood of irreparable harm. The appeals court conceded that "[t]he parties' experts disagreed over virtually every factual issue relating to possible environmental harm, including the likelihood of genetic contamination," *id.* at 9a, but, curiously, agreed with the district court's finding that Petitioners "had [not] established any material issues of fact" requiring a hearing. The panel agreed with the district court's decision "to avoid the catch-22 situation where an evidentiary hearing would require it to perform the same type of extensive inquiry into environmental effects that the ordered EIS will require the government agency to perform." *Id.* at 17a-18a.

Judge Smith dissented on whether Petitioners were entitled to an evidentiary hearing before the district

court could enter a permanent injunction. *Id.* at 20a-26a. He explained that, under Federal Rule of Civil Procedure 65, a district court must hold an evidentiary hearing before issuing an injunction unless the material facts are undisputed or the adverse party waives its right to a hearing. *Id.* at 20a-21a (citing *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988)). Because neither exception applied in this case, Judge Smith would have held that the district court erred in refusing Petitioners' request for an evidentiary hearing. *Id.* at 21a-22a.

SUMMARY OF THE ARGUMENT

This Court has long recognized that "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses." *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970). Because it is such an extraordinary form of relief, an injunction requires an evidentiary hearing unless the facts are undisputed or the adverse party has waived its right to a hearing. Here, the district court refused Petitioners' request for an evidentiary hearing, concluding that holding a hearing on the question of irreparable harm would require it to engage in precisely the same inquiry that APHIS would perform in its EIS.

Contrary to the district court's reasoning, an agency's evaluation of environmental harm under NEPA is *never* the same inquiry as a court's determination of irreparable harm to the party seeking an injunction. The traditional standard for granting an injunction requires a plaintiff to show that he, not the environment, will suffer irreparable injury. In other words, the district

court improperly conflated the purpose of an EIS under NEPA with the purpose of an evidentiary hearing before the issuance of an injunction. Simply put, a judge cannot avoid the venerable procedural safeguards of equity merely because an administrative agency may later engage in a slightly similar analysis. And a district court may not issue a blanket, nationwide injunction without first resolving genuine disputes over the likelihood of irreparable harm under narrower, more tailored protective measures.

Despite acknowledging the general rule that a district court must hold an evidentiary hearing before issuing a permanent injunction, the Ninth Circuit affirmed the district court's denial of Petitioners' request for an evidentiary hearing. In doing so, the appeals court purported to excuse the requirement for an evidentiary hearing because Petitioners failed to establish any disputed issues of material fact. But in the same opinion, the appeals court conceded that "[t]he parties' experts disagreed over virtually every factual issue relating to possible [irreparable] harm." Pet. App. at 9a. To the extent that the appeals court considers factual disputes over the likelihood of irreparable harm in the "run of the mill" NEPA case immaterial to the propriety of an injunction, such a conclusion has no legal basis. Contrary to the Ninth Circuit's view, a court contemplating an injunction under NEPA must always determine whether irreparable harm will follow in the absence of the injunction.

The appeals court also attempted to justify depriving Petitioners an evidentiary hearing because a permanent injunction under NEPA is temporary, lasting only until the agency concludes its preparation of an EIS.

But the right to an evidentiary hearing before an injunction can issue has *never* been linked to the expected duration of the injunction. Regardless of duration, every injunction is an "extraordinary and drastic remedy" that cannot be awarded as of right. Indeed, the right to a hearing attaches with equal force to both preliminary and permanent injunctions, and this Court has refused to recognize different standards of equity based on an injunction's expected duration.

Finally, this Court has repeatedly rejected the suggestion that a mere procedural violation of a statute requiring environmental review justifies an injunction against the underlying conduct until that environmental review is completed. Rather, in evaluating the appropriateness of granting an injunctive remedy for a statutory violation, this Court has consistently looked to the statute's substantive scheme and purpose. NEPA, the statute at issue here, is purely procedural and imposes no substantive environmental obligations on a federal agency's decision-making. Because any NEPA deficiency is being cured by APHIS's completion of an EIS, NEPA's narrow procedural purpose does not warrant a substantive injunction in this case.

ARGUMENT

I. PETITIONERS WERE ENTITLED TO AN EVIDENTIARY HEARING ON THE LIKELIHOOD OF IRREPARABLE HARM

A. An Agency's Evaluation of Environmental Harm Under NEPA Is Not The Same Inquiry as a Court's Determination of Irreparable Harm

It has long been "a cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings. Any other course would be contrary 'to the spirit which imbues our judicial tribunals prohibiting decision without hearing.'" *United States v. Microsoft Corp.*, 253 F.3d 34, 101 (D.C. Cir. 2001) (quoting *Sims v. Greene*, 161 F.2d 87, 88 (3d Cir. 1947)), *cert denied*, 534 U.S. 952 (2001). As this Court has acknowledged, "[i]n almost every setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses." *Goldberg v. Kelly*, 397 U.S. 254, 269 (1970).

It is "the duty of a court of equity granting injunctive relief to do so upon conditions that will protect all . . . whose interests the injunction may affect." *Inland Steel Co. v. United States*, 306 U.S. 153, 157 (1939). Most relevant here, "[a] party has the right to judicial resolution of disputed facts not just as to the liability phase, but also as to *appropriate relief*." *Microsoft Corp.*, 253 F.3d at 101 (emphasis added). All evidentiary conflicts "must be resolved by oral testimony since only by hearing the witnesses and observing their

demeanor on the stand can the trier of fact determine the veracity of the allegations . . . made by the respective parties." *Sims*, 161 F.2d at 88; *see Dopp v. Franklin Nat'l Bank*, 461 F.2d 873, 878-79 (2d Cir. 1972) (vacating injunction below because "a judge should not resolve a factual dispute on affidavits or depositions").

Indeed, the Ninth Circuit has itself recognized that "the entry or continuation of an injunction requires a hearing. Only when the facts are not in dispute, or when the adverse party has waived its right to a hearing, can that significant procedural step be eliminated." *Charlton v. Estate of Charlton*, 841 F.2d 988, 989 (9th Cir. 1988) (quoting *Prof'l Plan Exam'rs of New Jersey, Inc. v. Lefante*, 750 F.2d 282, 288 (3d Cir. 1984)). Other circuits agree. *See, e.g., McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1311-12 (11th Cir. 1998) ("Where the injunction turns on the resolution of bitterly disputed facts . . . an evidentiary hearing is normally required to decide credibility issues.") (quoting *All Care Nursing Serv. v. Bethesda Mem'l Hosp., Inc.*, 887 F.2d 1535, 1538 (11th Cir. 1989)); *Huntington v. March*, 884 F.2d 648, 654 (2d. Cir. 1989) (holding that the district court erred by failing to hold an evidentiary hearing prior to granting an injunction); *United States v. McGee*, 714 F.2d 607, 613 (6th Cir. 1983) ("Normally, an evidentiary hearing is required before an injunction may be granted.").

The need for an evidentiary hearing is especially acute where, as here, "[t]he parties' experts disagreed over virtually every factual issue." Pet. App. at 9a. But rather than carefully sift through the parties' contrary evidence, rule on Petitioners' evidentiary objections, or assess the viability of the parties' expert witness testimony, the district court refused to conduct an

evidentiary hearing even though it admitted it was "a close question of first impression" whether the alleged harms were even cognizable under NEPA. *Id.* at 27a. Instead, the court heard "oral argument" on Respondents' request for a permanent injunction. *Id.* at 58a-59a. At that argument, the court announced its view that it was under no obligation to resolve the parties' evidentiary dispute over the likelihood of irreparable harm:

> So I'm not an environmental agency. I'm not the person who has to look and analyze and try to figure out, does this have an environmental impact or doesn't it. . . . It just seems to me that . . . I could be like a super environmental agency engaged in balancing all these different factors and coming to particular conclusions, which I feel particularly ill suited to do, number one. And number two, it isn't my job. . . . I should stop things in place until the Government has discharged its duty given to it by the right of Congress of the United States.

Id. at 417a.

In its permanent injunction order, the district court acknowledged that "intervenors have requested an evidentiary hearing, apparently so the Court can assess the viability of its witnesses' opinions regarding the risk of contamination if APHIS's proposed conditions are imposed." *Id.* at 67a. Nevertheless, the court reinforced the view it announced at oral argument, explaining that it "did not need to conduct an extensive inquiry,

involving scientific determinations, to determine what interim measures are necessary to protect the environment 'while the [government] conducts studies in order to make the very same scientific determinations.'" *Id.* at 17a. Ultimately, the district court concluded that holding an evidentiary hearing would require it "to engage in precisely the same inquiry [that] APHIS failed to do and must do in an EIS." *Id.*

But an agency's evaluation of environmental harm under NEPA is *never* the same inquiry as a court's determination of irreparable harm to the party seeking an injunction. Indeed, the traditional standard for granting an injunction "requires the plaintiff to show that in the absence of its issuance, *he will suffer* irreparable injury." *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) (emphasis added). Thus, to obtain an injunction, plaintiffs must demonstrate that *they*--not the environment--will suffer irreparable harm. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (emphasizing that Article III remedies must redress an "injury to the plaintiff" rather than an "injury to the environment"); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 563 (1992) (holding that a plaintiff challenging a federal action must prove that she is "'directly' affected apart from [her] 'special interest' in th[e] subject").

In other words, the district court improperly conflated the purpose of an EIS under NEPA with the purpose of an evidentiary hearing before issuing an injunction. Under NEPA, "the purpose of an environmental impact statement is to provide full and fair discussion of significant environmental impacts and to inform decision makers and the public of reasonable

alternatives that would minimize adverse environmental impacts." *California ex rel. Lockyer v. USDA*, 575 F.3d 999, 1012 (9th Cir. 2009). In contrast, the goal of an evidentiary hearing before granting injunctive relief is to arrive at a "'nice adjustment and reconciliation' between the [parties'] competing claims" of injury resulting from "the granting or withholding of the injunction," by "balanc[ing] the conveniences of the parties and possible injuries to them" and "mould[ing] each decree to the necessities of the particular case." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (citations omitted). By itself, an agency's failure to conduct the "hard look" required by NEPA before undertaking a particular action does not constitute irreparable injury to the plaintiff. *See Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009) (holding that "depravation of a procedural right" is "insufficient"). And the mere fact that a government agency has been directed to conduct an independent review of environmental harm under NEPA provides no justification for ignoring this Court's holding that "an injunction should issue only where the intervention of a court of equity is essential in order effectually to protect property rights against injuries otherwise irremediable." *Romero-Barcelo*, 456 U.S. at 312.

Neither APHIS nor the USDA is a court of equity, and an administrative agency's subsequent analysis of environmental impacts under NEPA can never substitute for an evidentiary hearing to establish the grounds for injunctive relief in the first place.[2] In every

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[2] Devoid of any analysis of the Federal Rules or the history of equitable practice, the government's brief ignores this fundamental distinction, suggesting that an evidentiary hearing is unnecessary because the likelihood of success in an APA challenge

NEPA case, determining whether an injunctive remedy is appropriate requires a careful judicial balancing of the relative harm to the parties. *See, e.g., Lands Council v. McNair*, 537 F.3d 981, 1005 (9th Cir. 2008) (en banc) ("Our law does not . . . allow us to abandon a balance of harms analysis just because a potential environmental injury is at issue."). Likewise, as Petitioners rightly point out, a court's injunctive relief analysis is subject to a substantive narrow tailoring requirement, which simply does not apply for an agency performing an EIS under NEPA. *See* Pet. Br. at 47-48. Simply put, a judge cannot avoid the venerable procedural safeguards of equity merely because an administrative agency may later engage in a slightly similar analysis. And a district court may not issue a blanket, nationwide injunction without first resolving genuine disputes over the likelihood of irreparable harm under narrower, more tailored protective measures.

Here, the district court refused to allow Petitioners to confront and cross examine Respondents' expert witnesses. Likewise, the district court failed to analyze APHIS's and Petitioners' expert testimony as to the unlikelihood of any harm to Respondents under the government's proposed stewardship measures. Without the benefit of such an evidentiary hearing, the district court simply preferred Respondents' papers to those of

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is typically based solely on the administrative record. *See* U.S. Br. at 38-43. But the likelihood of success was no longer in dispute at the remedies stage, where the district court's adjudication of the parties' dispute over the appropriate remedy could be resolved only by reference to materials outside the administrative record. And "[a] hearing on the merits . . . does not substitute for a relief-specific evidentiary hearing." *Microsoft Corp* , 253 F.3d at 101.

Petitioners. *See Sims*, 161 F.2d at 88 ("If witnesses are not heard, the trial court will be left in the position of preferring one piece of paper to another."). In so doing, the district court violated "the cardinal principle of our system of justice that factual disputes must be heard in open court and resolved through trial-like evidentiary proceedings." *Microsoft Corp.*, 253 F.3d at 101.

B. The Court of Appeals Erred In Affirming the Denial of an Evidentiary Hearing

Despite acknowledging that "generally, a district court must hold an evidentiary hearing before issuing a permanent injunction unless the adverse party has waived its right to a hearing or the facts are undisputed," Pet. App. at 17a, the appeals court purported to review the district court's factual "findings" and explicitly endorsed the district court's deprivation of Petitioners' right to an evidentiary hearing. *Id.* at 14a. In doing so, the Ninth Circuit offered two independent reasons why Petitioners were not entitled to a full evidentiary hearing before the injunction could issue. Both contentions are unavailing.

First, the court of appeals did not believe Petitioners "had established any material issues of fact that were in dispute in the case before the court." *Id.* at 17a. Yet even a cursory review of the record below belies this suggestion. In response to Respondents' request for a blanket, nationwide injunction, Petitioners offered voluminous evidence demonstrating that, under APHIS's proposed stewardship measures, the possibility of cross-pollination from Roundup Ready alfalfa seed fields to conventional alfalfa seed fields would be "extremely low"

and "de minimus." *Id.* at 227a-229a, 234a-235a. Specifically, Petitioners' experts estimated that the level of seed-to-seed transmission would be somewhere between 0.01% and 0.03%, if it occurred at all. *Id.* at 162a-163a. Petitioners' evidence also established that seed-to-hay cross-pollination was even less likely, since there has never been a single reported incident of cross-pollination from Roundup Ready alfalfa seed fields to conventional alfalfa hay crops. *Id.* at 408a-409a.

For their part, Respondents offered various second-hand anecdotal accounts of alleged cross-pollination, including declarations from farmers who subjectively feared that cross-pollination would occur. Even if accepted as true, however, Respondents' evidence suggested only that cross-pollination was possible, not that it would be likely under APHIS's proposed mitigation measures. *Id.* at 403a-407a. Petitioners objected to much of Respondents' evidence as inadmissible hearsay, but the district court never ruled on those objections and summarily denied Petitioners' request to cross-examine Respondents' experts. *Id.* at 60a-79a.

As the record makes clear, the parties sharply disputed whether and to what extent Respondents would be irreparably harmed in the absence of a blanket injunction. Indeed, in the same opinion in which it announced that there were no unresolved issues of material fact, the appeals court conceded that "[t]he parties' experts disagreed over virtually every factual issue relating to possible [irreparable] harm, including the likelihood of genetic contamination." *Id.* at 9a. Because the Ninth Circuit explicitly recognized that the parties disagreed over virtually every fact related to the

likelihood of irreparable harm, the only logical interpretation of its ruling is that the appeals court considers factual disputes over the likelihood of irreparable harm in the "run of the mill" NEPA case immaterial to the propriety of an injunction. Such a conclusion has no basis in the law.

Indeed, this Court has repeatedly articulated the burden a plaintiff must satisfy to obtain a district court's entry of a permanent injunction. "According to well-established principles of equity," a plaintiff seeking a permanent injunction must demonstrate, among other things, that "it has suffered an irreparable injury" and "that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006); *see also Romero-Barcelo*, 456 U.S. at 312 ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies.").

Nor is the need to establish a likelihood of irreparable harm somehow obviated in the NEPA context. Rather, in every NEPA case (as in every other case), a plaintiff must demonstrate that he is likely to suffer irreparable injury before an injunction can obtain. *See Winter*, 129 S. Ct. at 375 ("Our frequently reiterated standard requires plaintiffs seeking [injunctive] relief to demonstrate that irreparable injury is likely in the absence of an injunction."). The appeals court's opinion is inconsistent with this Court's understanding of injunctive relief as "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 376 (citing *Mazurek v.*

Armstrong, 520 U.S. 968, 972 (1997) (per curiam)). As *Winter* confirms, a court contemplating an injunction under NEPA must always determine whether irreparable harm will follow in the absence of an injunction. Thus, contrary to the appeals court's view, disputed facts as to whether such harm is irreparable are always material.

Second, the appeals court held that a NEPA case differs from the "normal injunctive setting" because, unlike a "typical" injunction of "indefinite duration," an injunction under NEPA is temporary, lasting only until the agency concludes its preparation of an EIS. Pet. App. 17a-18a. But the right to an evidentiary hearing before an injunction can issue has *never* been linked to the expected duration of the injunction. Regardless of duration, every injunction is an "extraordinary and drastic remedy" that is "never awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008); *Microsoft Corp.*, 253 F.3d at 101 ("Other than a temporary restraining order, no injunctive relief may be entered without a hearing.") (citing Fed. R. Civ. P. 65).

Indeed, the right to a hearing attaches with equal force to *preliminary* injunctions, which by definition are temporary in nature. *See, e.g., Fengler v. Numismatic Americana, Inc.*, 832 F.2d 745, 747 (2d Cir. 1987) (holding that a hearing is required for a preliminary injunction if essential facts are in dispute); *Medeco Security Lock, Inc. v. Swiderek*, 680 F.2d 37, 38 (7th Cir. 1982) ("It is well established that, in general, a motion for a preliminary injunction should not be resolved on the basis of affidavits alone. Normally, an evidentiary hearing is required to decide credibility issues."); *Dopp*, 461 F.2d at 878-79 (vacating preliminary injunction because "the judge, without holding an evidentiary

hearing, resolve[d] the bitterly disputed facts in favor of the party who ha[d] the burden of establishing his right to preliminary relief"); *Sims*, 161 F.2d at 88 ("The issuance of a preliminary injunction under such circumstances is contrary not only to the Rules of Civil Procedure but also to the spirit which imbues our judicial tribunals prohibiting decision without hearing.").

Further, a permanent injunction is inherently "temporary" in that it will expire once the violation is remedied or the controversy is mooted. As this Court has recently held, once a violation has been remedied, "continued enforcement of the order is not only unnecessary, but *improper*." *Horne v. Flores*, 129 S. Ct. 2579, 2595-96 (2009) (emphasis added). Even when issued for grave constitutional violations, permanent injunctions "are not intended to operate in perpetuity." *Bd. of Educ. of Okla. City Pub. Schs. v. Dowell*, 498 U.S. 237, 248 (1991); *see also McGee*, 714 F.2d at 613 (recognizing that an evidentiary hearing is required for a permanent injunction unless there are no triable issues of fact).

Accordingly, the Ninth Circuit's strained attempt to conjure up different standards of equity for permanent versus preliminary injunctions--a distinction without a difference--fails as a matter of law and logic. *See Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 546 n.12 (1987) ("We fail to grasp the significance of this distinction. The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.").

II. NEPA'S PURPOSE DOES NOT MANDATE A SUBSTANTIVE INJUNCTION FOR A CURABLE PROCEDURAL DEFAULT

The appeals court affirmed the district court's ruling on the assumption that a NEPA violation should typically result in an injunction against an ongoing federal project until the agency has fully complied with NEPA. Under the appeals court's reasoning, since the finding of a NEPA violation almost always results in a requirement that the defendant agency conduct an additional environmental review, an injunction should issue "absent unusual circumstances" in the "run of the mill NEPA case." Pet. App. 12a, 55a-56a. As Judge Smith accurately noted in his dissent, "[t]here aren't many environmental cases that don't fit into the majority's newly created" rule for injunctions. *Id.* at 102a.

As explained above, however, this Court has unanimously rejected the notion that an injunction should issue except in an "unusual case," under "exceptional circumstances," or "in rare instances," as contrary to traditional principles of equity. *eBay Inc.*, 547 U.S. at 392-94 ("[This] Court has consistently rejected invitations to replace traditional equitable considerations with a rule that an injunction automatically follows [a statutory violation]"). More importantly, this Court has repeatedly rejected the notion that a mere procedural violation of an environmental statute automatically justifies an injunction of the underlying conduct pending further environmental review.

Rather, in evaluating the appropriateness of granting an injunctive remedy for a statutory violation, this Court has consistently looked to the statute's substantive scheme and purpose. The Court first announced this approach in *Weinberger v. Romero-Barcelo*, which involved an injunction issued to remedy a violation of the Clean Water Act (CWA), 33 U.S.C. §§ 1251-1376. *See* 456 U.S. at 305. In that case, the First Circuit reversed the district court's denial of an injunction to remedy the Navy's failure to obtain a national pollution discharge elimination system (NPDES) permit before conducting weapons training on an island off the coast of Puerto Rico. *Id.* at 310-11. Consulting the "substantive scheme and purpose" of the CWA, the Court emphasized that an injunction was not necessary to accomplish the statute's purpose, which the Navy could fulfill by simply complying with the permit requirement. *Id.* at 314-15. Thus, the Court agreed with the district court, which had ordered the Navy to apply for a permit but allowed the Navy to continue its activities without a permit. *Id.*

Six years later, in *Amoco Production Co. v. Village of Gambell*, this Court revisited the question of injunctive relief in the environmental context. In that case, the Ninth Circuit reversed the district court's denial of an injunction for a violation of the Alaska National Interest Lands Conservation Act (ANILCA), 43 U.S.C. §§ 1602-1784. Even though the agency had likely violated ANILCA by issuing oil and gas leases without first conducting environmental studies required by ANILCA, this Court reversed the Ninth Circuit, holding that "the Ninth Circuit erroneously focused on the statutory procedure rather than the underlying substantive policy the process was designed to effect."

Amoco Prod. Co., 480 U.S. at 544. Analyzing ANILCA's substantive requirements, the Court ruled that the Ninth Circuit's requirement of an injunction was improper because "compliance [with ANILCA] could be obtained through the simple means of an order to the responsible federal officer to comply," rather than by enjoining all activity until compliance had been achieved. *Id.* at 543 n.8.

This Court has long recognized that NEPA is a purely procedural statute that imposes no substantive environmental obligations on a federal agency's decision-making. *See, e.g., Winter*, 129 S. Ct. at 376 ("NEPA imposes only procedural requirements"); *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989) ("[I]t is now well settled that NEPA itself does not mandate particular results."). While "[o]ther statutes may impose substantive environmental obligations on federal agencies," NEPA merely "prohibits uninformed—rather than unwise—agency action." *Id.* Indeed, "[w]hether the federal agency ends up taking the 'major federal action' at issue has nothing to do with NEPA compliance; NEPA only requires that the agency follow a certain process in deciding whether to take the action." *Sierra Club v. Van Antwerp*, 526 F.3d 1353, 1361 (11th Cir. 2008).

Because NEPA is concerned solely with ensuring an agency's fidelity to procedure, "[s]ubstantive issues like whether to grant the permits and what mitigation conditions to adopt are *irrelevant* to NEPA compliance." *Id.* at 1362 (emphasis added). So long as the proper procedure is followed, then, an agency is simply not constrained by NEPA, regardless of the alleged severity of environmental harm. *See, e.g., Robertson*, 490 U.S. at

350 ("[I]t would not have violated NEPA if the Forest Service, after complying with the Act's procedural prerequisites, had decided that the benefits to be derived from downhill skiing at Sandy Butte justified the issuance of a special use permit, notwithstanding the loss of 15 percent, 50 percent, or even 100 percent of the mule deer herd."); *Van Antwerp*, 526 F.3d at 1361-62 ("In this case, it would not violate NEPA if the EIS noted that granting the permits would result in the permanent, irreversible destruction of the entire Florida Everglades.").

At most, NEPA requires only that a federal agency prepare an EIS for every "major Federal action[] significantly affecting the human environment." 42 U.S.C. § 4332(2)(C). Beyond forcing an agency to take a "hard look" at environmental impacts, a court acting pursuant to NEPA "cannot 'inject itself within the area of discretion of the executive as to the choice of action to be taken.'" *Strycker's Bay Neighborhood Council, Inc. v. Karlen*, 444 U.S. 223, 227-28 (1980) (per curiam) (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 410 n.21 (1976)); *see also Earth Island Inst.*, 129 S. Ct. at 1151 (holding that mere "depravation of a procedural right" is "insufficient" to establish harm to plaintiff).

In light of NEPA's explicitly narrow procedural purpose, nothing in the text of NEPA mandates an injunction against all work on a federal project until the federal agency has taken NEPA's "hard look" at environmental impacts. If a federal agency fails to take NEPA's mandated "hard look" at environmental impacts, the most appropriate remedy is to require the agency to take that "hard look." Here, the purpose of NEPA is being achieved through APHIS's extensive

environmental assessment during the completion of an EIS. In the interim, NEPA's purpose does not justify a blanket, nationwide injunction against all further use of Roundup Ready alfalfa. And because any NEPA deficiency is being cured by APHIS's completion of an EIS, the procedural purpose of NEPA does not warrant a substantive permanent injunction against the further use of Roundup Ready alfalfa.

CONCLUSION

Amici curiae request that the Court reverse the judgment below.

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Date: March 8, 2010

Counsel wish to thank Corbin Barthold, a second-year student at the University of California Berkeley School of Law, for his assistance in preparing this brief.